GUIDANCE IN THE RULEMAKING PROCESS: EVALUATING PREAMBLES, REGULATORY TEXT, AND FREESTANDING DOCUMENTS AS VEHICLES FOR REGULATORY GUIDANCE

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ADMINISTRATIVE CONFERENCE
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Contents

Introduction

In the past two decades, the use of guidance—nonbinding statements of interpretation, policy, and advice about implementation—by administrative agencies has prompted considerable interest from executive branch officials, committees in Congress, agency officials, and commentators. Most of this attention has been directed toward "guidance documents,"[1] freestanding, nonbinding policy and interpretive statements issued by agencies. Policymakers and commentators have expressed concern that agencies are relying on guidance in ways that circumvent the notice-and-comment rulemaking process; in particular, the worry is that with the increased analytical and justificatory burdens of notice-and-comment rulemakings, agencies have turned to guidance as a way to establish norms without the participation benefits and explanatory burdens of the notice-and-comment process.[2]

Concern about agency reliance on guidance is also evident in the Supreme Court's doctrines governing the standards of judicial review of agency action. Based in part on the preference for policy formulation through rulemaking and other more formal processes, in

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[1] OFFICE OF MANAGEMENT AND BUDGET, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES, 72 FED. REG. 3432, 3439 (Jan. 25, 2007) [hereinafter *OMB's Good Guidance Bulletin*].

[2] For instance, in 1992, the Administrative Conference of the United States (ACUS) recommended that agencies provide affected persons an opportunity to challenge the wisdom of a guidance document or policy statement before the statement is applied to persons affected. Admin. Conf. of the United States, Agency Policy Statements, Recommendation 92-2, 57 Fed. Reg. 30,103 (June 18, 1992). The ACUS Recommendation commented, "The Conference is concerned . . . about situations in where agencies issue policy statements which they treat or which are reasonably regarded by the public as binding . . . .[but these pronouncements do] not offer the opportunity for public comment . . ."). In 2007, President Bush issued an executive order which subjected significant guidance documents to regulatory review based on similar concerns. *See* Exec. Order No. 13,422, 3 C.F.R. 191 (2008). President Obama revoked Executive Order 14,422, see Exec. Order No. 13,497, 3 C.F.R. 218 (2010), but as discussed below, *see* Memorandum from Peter Orzag, Dir. Office of Mgmt. & Budget, to Heads and Acting Heads of Exec. Dep'ts and Agencies (Mar. 4, 2009) [hereinafter "Orzag Memorandum"] (available at http://www.whitehouse.gov/sites/default/files/omb/assets/ memoranda_fy2009/m09-13.pdf), significant guidance is still subject to regulatory review. In 2007, OMB issued a "Final Bulletin for Agency Good Guidance Practices" which requires agencies to provide a means for comment on certain significant guidance documents, see *OMB's Good Guidance Bulletin*, *supra* note 1, and this Bulletin remains in effect. Committees in Congress have expressed concerns that agencies are inappropriately relying on guidance. *See, e.g.*, COMM. ON GOV'T REFORM, 106TH CONG., NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009, at 9 (2000) ("[A]gencies have sometimes improperly used guidance documents as a backdoor way to bypass the statutory notice-and-comment requirements for agency rulemaking . . ."); *cf.* The Regulatory Accountability Act of 2013, S. 1029, 113th Cong. (2013) (Section 706(d) would overrule *Auer* deference to agency interpretations of their own regulations); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 166 (2000) (arguing that agencies are avoiding ossified rulemaking process by use of nonbinding guidance). As I discuss below, recent empirical research calls into question empirical basis for this theory of strategic substitution of guidance documents for rules. *See infra* Part II.B.

2001, the Supreme Court announced a general presumption that to qualify for *Chevron* deference,[3] agency interpretations of the statutes the agency administers must be issued through relatively formal processes, such as notice-and-comment rulemaking.[4] That 2001 decision, *United States v. Mead Corp.*,[5] gives agencies incentives to act through notice-and-comment as opposed to guidance documents if they seek to trigger *Chevron* deference in review of their actions. In addition, in the last two years, three members of the Supreme Court have announced their interest in reconsidering the longstanding doctrine identified with *Bowles v. Seminole Rock & Sand Co.*[6] and *Auer v. Robbins*,[7] under which the reviewing courts must accept agency interpretation of their regulations unless plainly erroneous or inconsistent with the regulation.[8] In the same time period, the Supreme Court denied deference to an agency interpretation of its own regulation that appeared in a litigation brief.[9] These decisions suggest a narrowing of deference available to agencies when they take interpretive positions or issue guidance informally and *post hoc*.

This multi-decade debate about guidance and its relationship to notice-and-comment rulemaking has largely passed over the function and varieties of *contemporaneous guidance*—that is, guidance that agencies provide about the meaning of their rules in the rulemaking process. Contemporaneous guidance appears in three main forms. First, agencies provide guidance about the meaning and application of their rules in explanatory "statement[s] of their basis and purpose,"[10] statements which constitute the bulk of the regulatory "preambles" issued with final rules. Second, they provide guidance about the application and interpretation of their regulations in the Code of Federal Regulations, in notes and examples, and appendices that appear in the Code of Federal Regulations. Third, at the same time that agencies promulgate their regulations, they sometimes issue freestanding guidance documents. Contemporaneous guidance has a fundamental fair-notice benefit: It furnishes the public and regulated entities the agency's

[3] Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837, 843-44 (1984).
[4] *United States v. Mead Corp.*, 533 U.S. 218, 230-31 (2001) (noting that agency decisions decided in notice-and-comment qualify for application of *Chevron*).
[5] *Id.*
[6] 325 U.S. 410 (1945).
[7] 519 U.S. 452 (1997). While this doctrine was traditionally associated with *Seminole Rock*, since 1997 the Supreme Court and other courts have frequently attributed it to *Auer*, *see, e.g.*, *Talk Am., Inc. v. Mich. Bell Tel. Co.*, 131 S. Ct. 2254, 2265–66 (2011) (Scalia, J., concurring) (noting that the *Seminole Rock* doctrine has recently been attributed to *Auer*), despite the fact that *Auer* involved a straightforward application of *Seminole Rock*, *see Auer*, 519 U.S. at 461 (relying on *Seminole Rock* with little ado).
[8] Decker v. Northwest Envt'l Def. Center, 133 S. Ct. 1326 (2013); *id*. at 1338 (Roberts, C.J., and Alito, J., concurring) (noting that it "may be appropriate to reconsider" *Seminole Rock/Auer* in another case); *id.* at 1339, 1442 (Scalia, J.) (concurring in part and dissenting in part) (urging the Court to overturn *Seminole Rock/Auer*).
[9] *See* Christopher v. SmithKline Beecham Corp., 132 S. Ct. 2156, 2166–68 (2012) (concluding that "general rule" of granting *Auer* deference to interpretations in litigation briefs did not apply in these circumstances of the case in view of fair notice concerns).
[10] 5 U.S.C. § 553 (2012).

understanding of the regulation at the time of issuance, reducing some of the uncertainty incident to any new regulatory change, as opposed to later in time or in the context of an enforcement proceeding.[11]

The neglect of contemporaneous guidance in debates about guidance and rulemaking has practical implications along four dimensions. First, and at a most basic level, there has been little dialogue among policymakers or commentators about the best practices for providing guidance in the rulemaking process. Agencies have adopted a diverse set of practices. While uniformity is not necessary or a value to unreflectively demand of a practice as diverse and wide-ranging as rulemaking, the self-conscious choices that some agencies make about how to issue contemporaneous guidance can be a source of information and insight to other agencies. One aim of this Report is to catalogue the variety of agency practices, and legal regime that governs them, as a prompt to reflection about those that best suit particular rulemaking environments.

Second, while many agencies openly embrace the guidance function of preambles, other agencies treat their preambles as unrelated to, and performing an entirely different function than, their "guidance documents." But by treating preambles as occupying a functionally and conceptually distinct silo from guidance, some agencies neglect the basic guidance function of the "statement of [] basis and purpose," exclude preambles from their general policies on guidance, fail to include reference to preambles in their official compilations of guidance, and web postings of guidance. Many agencies could also do more to make guidance they provide in preambles easier to locate, for instance, by organizing them to make it easier for the reader to locate the most salient discussions of each element of the regulation, limiting the extent to which they rely on discussions of the rule in notice of proposed rulemaking (NPRM) which can require the reader to integrate two separate statements of the rule, and/or by including hyperlinks to the preambular guidance on electronic versions of their regulatory texts. A second aim of this Report is to suggest reasons why contemporaneous guidance deserves a place at the table in debates and agency choices about guidance and rulemaking, and to make several specific supporting recommendations in this regard.

Third, at the other extreme, in some cases, agencies treat the text of their preambles and the text of their rules as functional equivalents. Thinking about preambles as a source of guidance also prompts inquiry into the boundaries of appropriate use of the preamble.

[11] This is not to say that a broad variety of circumstances—uncertainty about how a regulation will affect those subject to it, changes in technological, business, environmental or other conditions, newly acquired expertise or studies, constraints on agency staff time, etc.—all provide a justification for issuing post hoc guidance. But if all other considerations are equal, contemporaneous guidance has a fair notice benefit.

A third aim of the Report is to identify the residual need to insist on the distinctions between preamble and regulatory text.

Fourth, agencies have unrealized opportunities for including notes and examples in the Code of Federal Regulations (CFR) or more extensive guidance published as appendices to the CFR. Where the agency knows that the regulated public relies primarily on the CFR to understand its obligations, there is a strong need for uniformity in guidance, and that guidance does not need to be frequently amended including notes and examples in the CFR or more extensive guidance in an appendix to the CFR can enhance the visibility of this agency advice. The Report also seeks to identify some of those opportunities.

This Report is organized as follows. Part I defines guidance and discusses the scope of the inquiry and methodology of the Report. Part II gives a brief overview of notice-and-comment rulemaking and the role of guidance in the rulemaking process. Part III describes the legal regime governing guidance in preambles, regulatory text, and contemporaneous, separately issued documents. The summary provided in Part III illustrates the continuities between guidance issued in a preamble, regulatory text, and separate documents, highlighting the need for self-conscious choice by agencies about the forms in which they issue guidance. Part IV offers a description of the varieties of contemporaneous guidance that agencies issue. Part V makes several recommendations to federal agencies. Given that regulations have long since outnumbered statutes,[12] it is worth examining the promise and challenges that contemporaneous guidance faces.

I. Definition of Guidance and Scope of Inquiry

A. Definition and Dimensions of Guidance

It is first important to define what is meant by the word "guidance" in this Report. By "guidance" this Report refers to (i) *agency statements outside of those appearing in regulatory text that pertain to the meaning or interpretation of the agency's regulations or to advice about how to comply with the agency's regulations*, and (ii) *agency statements appearing in regulatory text that are designed to guide the application or interpretation of the regulation, such as examples or official commentaries*.

[12] *See* CORNELIUS M. KERWIN & SCOTT P. FURLONG, RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY 13-21 (4th ed. 2011) (documenting, in both number of rules and pages of the *Federal Register* devoted to federal regulations, a level of production that far exceeds comparable measures for federal legislation).

This definition departs from the most prominent definition of guidance which appears in the Office of Management and Budget's *Final Bulletin on Agency Good Guidance Practices* ("*OMB's Good Guidance Bulletin*")[13] in two important respects. Under *OMB's Good Guidance Bulletin,* a "guidance document" is "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue."[14] In contrast, this Report addresses only guidance about the meaning or application of *regulations*, not guidance about statutes or other sources of law. In that respect, this Report focuses on a narrower class of guidance that falls within the Bulletin's definition.

Second, this Report includes statements that appear in the regulation's text or are published in an appendix to the regulation's text as forms of guidance. Because these statements would qualify as "regulatory action[s]" under *OMB's Good Guidance Bulletin*'s definition of guidance, they would be excluded from its scope. Because statements that are similar in content can appear in a regulation's preamble, text, or a separately issued document, the broader definition used in this Report does not preclude consideration of these forms of guidance, and agencies' justifications for using them. But because "guidance" is so frequently associated with documents issued outside of the essential rulemaking documents, it is worth expressly emphasizing that under the definition of "guidance" used here, the guidance may appear in a preamble or the text of a regulation, not merely in separately issued documents.[15]

With guidance so defined, guidance can be classified on three dimensions:

1. Timing. Guidance can be provided at the time of the regulation's issuance or at a later time. Contemporaneous guidance would include guidance that appears in a preamble, the regulation's text, or documents issued at the same time as the regulation, such as compliance guides;[16] all other guidance is *post hoc*.

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[13] *OMB's Good Guidance Bulletin*, *supra* note 1. The definition of "guidance document" adopted in *OMB's Good Guidance Bulletin* is the same as that used in President Bush's Executive Order, Further Amendments to Executive Order 12866 on Regulatory Planning and Review, Executive Order 13,422, 72 Fed. Reg. 2763, 2762 (Jan. 23, 2007) (inserting Section 3(g) with this definition), which President Obama revoked. *See* Exec. Order No. 13,497, 3 C.F.R. 218 (2010).

[14] *See OMB's Good Guidance Bulletin*, *supra* note 1, at § I.3.

[15] Statements in preambles could be considered guidance documents even under the definition of guidance in the Executive Order because they are "an agency statement[s] of general applicability and future effect, other than a regulatory action, that sets forth a policy on a . . . regulatory or technical issue or an interpretation of . . . a regulatory issue." *Id.*

[16] Small Business Regulatory Enforcement Fairness Act, Pub. L. No. 104-121, § 212(a), 110 Stat. 873, codified at 5 U.S.C. § 601 nt. (2012).

2. Content. Guidance can take innumerable forms, including: providing (1) general advice about the meaning of particular words or provisions, (2) answers to frequently asked questions, (3) announcement of priorities of the agencies with regard to the enforcement of their regulations, (4) examples of calculations required under the regulations, and (5) examples of model forms.

3. Location. As noted above, guidance can also appear as part of different documents, most obviously including: (1) the regulation's preamble, (2) portions of the agency's reasoning stated in a Notice of Proposed Rulemaking (NPRM) adopted in the regulation's preamble, (3) the regulation text, such as in notes and examples, (4) an appendix to the regulation's text whether published in the Code of Federal Regulations (CFR) or not, or (5) documents issued separately from these core rulemaking documents.

B. Scope of Inquiry and Methodology

This Report focuses on this third dimension—the location of guidance. In almost every rulemaking, agencies face a choice regarding guidance. They can issue virtually identical advice and text in the regulation's preamble, the regulation's codified text or appendix, or in a separate document issued alongside the rule; guidance that appears in preambles in some rulemakings appears in regulatory text or separately issued documents in other rulemakings. The variation is not itself a cause for concern; the difference in the content of regulations, their audience, duration, and interaction with the surrounding legal landscape among many other factors may justify these different choices, even for a single agency. But because these different locations can have different legal effects, different modes of publication, and different ability to reach the regulated, it is worth examining the constraints on the agency's choices and the considerations that inform their best practices with regard to issuing contemporaneous guidance. Those questions are the focus of this Report.

The Report was conducted primarily through legal research and research on agencies' practices in providing contemporaneous guidance. As to agency practices, the research had two components. First, it involved text-based word searches of rulemakings conducted in the last five years by executive agencies that had promulgated economically significant regulations in the last 15 years. The focus on the last five years was to ensure study of current practices. The set of executive agencies that had issued an economically significant rule in the last 15 years is drawn from David Lewis and Jennifer Selin's

Sourcebook of the United States Executive Agencies.[17] This sample was chosen because it reflects a cross-section, at least of executive agencies, engaged in the most significant rulemakings. Second, with the assistance of Staff Counsel at ACUS in arranging contacts within those engaged in rulemaking at agencies, I also conducted half-hour phone interviews with counsel working on rulemaking in 12 agencies in January and February, 2014.[18] The Report includes discussion of examples of rulemakings from those agencies even if they were not among those identified for the word searches of agency practices. On February 10, 2014, I presented an overview of the project for brown bag discussion at ACUS headquarters attended by more than thirty other government lawyers working on rulemaking. The experience and insight of the lawyers with whom I spoke informed the recommendations and coverage of this Report.

II. Guidance and Rulemaking: A Brief Overview

To assess the appropriate role of guidance in rulemaking today, it first makes sense to begin with some background understanding of the place and prominence of guidance within and outside of notice-and-comment rulemaking proceedings.

A. The APA's Vision: The Dual Role of the Statement of Basis and Purpose -- Justification and Guidance

The Administrative Procedure Act (APA) provides a simple structure for notice-and-comment rulemaking, especially given the scope of federal lawmaking that now emerges through this process. Section 553 of the APA sets out three basic elements of notice-and-comment rulemaking.[19] First, section 553 requires publication of a "[g]eneral notice of proposed rulemaking" in the *Federal Register*, commonly referred to as an "NPRM."[20] Second, after publication of that required notice, the agency "shall give interested persons an opportunity to participate in the rule making through submission of

[17] DAVID E. LEWIS & JENNIFER L. SELIN, SOURCEBOOK OF UNITED STATES EXECUTIVE AGENCIES 132 (Table 20) (December 2012 First Edition). The following agencies fall in this category: USDA, DOC, DOD, DOED, HHS, DHS, HUD, DOI, DOJ, DOL, STAT, DOT, DTRS, DVA, EPA, EEOC, OMB, OPM, RRB, SBA, SSA.

[18] These agencies included the Board of Governors of the Federal Reserve System, Consumer Financial Protection Bureau, Department of Education, Department of Health and Human Services, Department of the Interior, Department of Transportation , Department of the Treasury, Equal Employment Opportunity Commission, Merit Systems Protection Board, Occupational Health & Safety Review Commission, Social Security Administration, and U.S. Coast Guard.

[19] 5 U.S.C. § 553 (2012). Section 553 provides a default process for rulemaking except in the rare case of a statute that requires the rulemaking be conducted through the APA's formal rulemaking procedure, *see id.* § 553 (noting that § 556 & § 557 apply when the rules are required by statute "to be made on the record and after opportunity for an agency hearing"), or when a statute specifies its own rulemaking procedure.

[20] 5 U.S.C. § 553(b) (2012).

written data, views, or arguments."[21] Third, after consideration of these comments, "the agency shall incorporate in the rules adopted a concise and general statement of their basis and purpose."[22] The APA exempts from these notice and consideration requirements "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice," among other exceptions, which are sometimes referred to as nonlegislative rules or guidance documents.[23]

Early understandings of the APA suggest that the statement of basis and purpose, which comprises much of what is commonly referred to as the regulation's "preamble," was intended to have a dual role: not only identifying the legal and factual basis for the rule, but also providing guidance on its meaning and import for the public and the courts. This message comes through clearly in the *Attorney General's Manual on the Administrative Procedure Act*.[24] Of the statement of basis and purpose, the Manual opines, "[t]he required statement will be important in that the courts and the public will be expected to use such statements in the interpretation of the agency's rules."[25] And the Manual goes on, "the statement is intended to advise the public of the general basis and purpose of the rules."[26] The APA's legislative history also supports this understanding. "The required statement of basis and purpose of rules issued," as both the House and Senate Judiciary Committee Reports commented on S.7 which became the APA, "should not only relate to the date so presented but with reasonable fullness explain the actual basis and objectives of the rule."[27]

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[21] *Id.* § 553(c).
[22] *Id*.
[23] *Id*. § 553(b)(3)(A).
[24] UNITED STATES DEPARTMENT OF JUSTICE, ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT (1947).
[25] *Id.* at 32.
[26] *Id*.
[27] H.R. REP. NO. 79-1980, at 259 (1946); S. REP. NO. 79-752, at 201 (1945), as available in ADMINISTRATIVE PROCEDURE ACT, LEGISLATIVE HISTORY, 79TH CONG., S. Doc. No. 79-248, 1944-46, 225 (1944-46). The Senate Report also contains as an appendix to the Attorney General's 1945 report on Senate Bill 7. The Attorney General's report stated the following in regards to the statement of basis and purpose:

> Section 4 (b), in requiring the publication of a concise general statement of the basis and purpose of rules made without formal hearing, is not intended to require an elaborate analysis of rules or of the detailed considerations upon which they are based but is designed to enable the public to obtain a general idea of the purpose of, and a statement of the basic justification for, the rules. The requirement would also serve much the same function as the whereas clauses which are now customarily found in the preambles of Executive orders.

S. REP. NO. 752, at 225 (1945) (also available in ADMINISTRATIVE PROCEDURE ACT, LEGISLATIVE HISTORY, 79TH CONG., 2D SESS., Doc. No. 248, 1944-46, 225 (1946).

The idea that the statement of basis and purpose was meant to apprise the public of the purpose and effect of the rule—that is, that it serve a guidance function—in addition to disclosing the basis for the rule has sound logic. The statement of basis and purpose is necessary for the procedural validity of the rule,[28] and constitutes the agency's authoritative statement of the rule's purposes and basis. Because the statement of basis and purpose is part and parcel of the agency's rulemaking, it makes sense these documents would help inform the public about the meaning and application of the rules they accompany, and that the public and courts would turn to them for those purposes.[29] As this Report documents, while many agencies continue to rely extensively on statements of basis and purpose to apprise the public of the application of their rules, the guidance function of these statements has had neither prominence, nor received much attention from government bodies or commentators.[30]

B. The Expanding Preamble, Ossification, and Separately Issued Guidance

Part of the explanation for the relative neglect of the guidance function of preambles is that agencies have come to devote more and more attention in their preambles to justifying the legal sufficiency of their rules. For some agencies, a clear legal division of labor has taken hold: The preamble is devoted almost entirely to the legal sufficiency of the regulation, and guidance is something the agency provides outside the rulemaking, in separately issued documents.

This development has been conventionally understood as a consequence of heightened judicial scrutiny review of the rationality of agency regulations that took hold in the late 1960s and early 1970s in the form of "hard look review" and has persisted ever since. Hard look review developed as a combination of two doctrinal elements. First, hard look review adopts the pre-APA administrative law requirement associated with *SEC v. Chenery Corp.*[31] (known as *Chenery I*), which stated that a reviewing court will uphold an agency's action based only on "the grounds upon which the agency acted in exercising its

[28] *See* Indep. U.S. Tanker Owners Comm. v. Dole, 809 F.2d 847, 852 (1987) (vacating a rule for inadequate statement of basis and purpose).
[29] *See* Kevin M. Stack, *Interpreting Regulations*, 111 Mich. L. Rev. 355 (2012) (defending reliance on agency preambles to interpret regulations).
[30] A few more comprehensive commentaries observe that agencies include statements of basis and purpose to explain their rules, but do not give the practice focused attention. *See, e.g.*, JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 337 (5th ed., 2012) ("Agencies often use the statement [of basis and purpose] to advise interested persons how the rule will be applied."); Richard J. Lazarus, *Meeting the Demands of Integration in the Evolution of Environmental Law: Reforming Environmental Criminal Law*, 83 GEO. L.J. 2407, 2437 (1995) (noting that lengthy preambles are just one sources of "underground environmental law" which also includes extensive guidance).
[31] 318 U.S. 80 (1943).

powers."[32] Second, hard look review embraces a relatively high standard for the quality of the reasons provided by the agency, despite statements by courts that arbitrary and capricious review is lenient or narrow.[33] When the *Chenery I* requirement for a contemporaneous statement of reasons is combined with a high standard for the quality of those reasons, the consequences for the agency are clear: For rules to survive judicial review, the agency must provide an extremely detailed justification of their grounds. The place for the agency to do so is in the rule's statement of basis and purpose.

The Supreme Court's decision in *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*[34] provides the classic application of hard look review. In *State Farm*, the Court set a high standard for the agency's level of express justification in its statement of basis and purpose in the rule. To avoid being arbitrary or capricious under section 706 of the APA, the agency must "examine the relevant data and articulate a satisfactory explanation for its action, including a 'rational connection between the facts found and the choice made.'"[35] An agency rule would normally be arbitrary and capricious if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[36] In *State Farm*, the Supreme Court reversed the agency's decision to rescind a rule under this standard, in part because the agency provided no consideration of one of the viable options within the ambit of the existing rule.[37] Since the *State Farm* decision, both the Supreme Court and the Courts of Appeals have emphasized that the vesting of wide power for agencies "carries with it a correlative responsibility for the agency to explain the rationale and factual basis for its decision,"[38] a duty that agencies discharge in their statements of basis and purpose. This duty not only includes evaluation of alternatives and explanation of the basis for the regulations adopted, but also a duty to discuss salient comments.[39] As a result, the agency's articulation of the grounds of its action and engagement with commentators in its statement of basis and purpose is necessary to the validity of the rule.

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[32] *Id.* at 95.
[33] *See, e.g.*, Citizens to Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971) (describing the standard as a "narrow" one); Muwekma Ohlone Tribe v. Salazar, 708 F.3d 209, 220 (D.C. Cir. 2013) (same).
[34] 463 U.S. 29 (1983).
[35] *Id.* at 43.
[36] *Id.*
[37] *Id.* at 51
[38] Bowen v. Am. Hosp. Ass'n, 476 U.S. 610, 627 (1986); *see also, e.g.*, Detsel by Detsel v. Sullivan, 895 F.2d 58, 63 (2d Cir. 1990).
[39] See, e.g., Am. Mining Cong. v. EPA, 965 F.2d 759, 771 (9th Cir. 1992).

As these doctrines of judicial review congealed in the contemporary hard look doctrine, the length of regulatory preambles has grown as measured by the average number of pages per final rule published in the *Federal Register*. Based on a study performed by the Congressional Research Service, the average number of Federal Register pages per final rule in 1976, 1977, 1978 was 1.7, 2.07, 2.2 respectively, whereas the averages in 2009, 2010, and that 2011 were 5.93, 6.97, and 6.91 respectively.[40] The common sense explanation is that the prospect of stringent judicial review, which requires the agency to "show it's work," has prompted agencies to devote more energy to writing elaborate statements of the legal sufficiency of their regulations in their preambles.[41] Other analysis requirements imposed on agencies also add to the explanatory obligations the agency must discharge in their preambles, including the analysis requirements imposed by Executive Order 12,866,[42] the Regulatory Flexibility Act,[43] the Paperwork Reduction Act, the National Environmental Policy Act of 1969, and the Unfunded Mandates Reform Act of 1995,[44] among other analysis and consultation requirements.

At the same time that the agency's duties of explanation—and actual explanations—of the basis for their rules in preambles has grown, the need for guidance as to the meaning and application of agency regulations has not gone away.

A common suspicion is that the increased costs associated with notice-and-comment rulemaking has given agencies incentives to look for alternative, less costly ways to establish policy or advise the public of the agency's understanding of the law. In particular, several commentators suggested that the high cost of notice-and-comment rulemaking has caused agencies to rely to a greater extent on separately issued guidance documents which need not proceed through notice-and-comment rulemaking,[45] effectively

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[40] MAEVE P. CAREY, CONG. RES. SERV. R43056, COUNTING REGULATIONS: AN OVERVIEW OF RULEMAKING, TYPES OF FEDERAL REGULATIONS, AND PAGES IN THE FEDERAL REGISTER, 17-18 (2013) (calculations produced by dividing the number of pages per final rule by the number of final rules, information reported in Table 6).

[41] *See, e.g.*, Richard J. Pierce, Jr. *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 65 (1997) [hereinafter "*Seven Ways*"] (suggesting that the stringent judicial gloss on the APA has "transform[ed] the simple, efficient notice and comment process into an extraordinarily lengthy, complicated, and expensive process," discouraging agency use of rulemaking); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1401 (1992) (attributing the "Herculean effort of assembling the record and drafting a preamble" to heightened judicial scrutiny of rulemaking).

[42] Exec. Order No. 12,866, 3 C.F.R 638 (1994). For a copy of this Regulatory Planning and Review Executive Order as amended, see 5 U.S.C. § 601 notes.

[43] 5 U.S.C. § 604(a)(2) (2012) (requiring agencies to state changes made in rule in response to comments).

[44] 2 U.S.C. § 1532(a)(5)(A) (2012) (requiring agencies to respond to comments from state and local governments).

[45] *See* 5 U.S.C. § 553(b) (2012) (excepting interpretative rules and general statements of policy from notice and comment requirements).

substituting guidance documents for rulemaking.[46] Recent empirical investigations call into question this suggestion that agencies rely on guidance documents to avoid the burdens of notice-and-comment rulemaking. In a study of the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Federal Communications Commission (FCC), Occupational Safety and Health Administration (OHSA), and the Internal Revenue Service (IRS), between 1996 and 2006, Connor Raso found that agencies do not increase their issuance of guidance strategically,[47] and that the body of significant legislative rules issued still dwarfs that of significant guidance.[48] In an extensive study of the Department of the Interior, Jason and Susan Webb Yackee also found no support for increased reliance on nonlegislative rules between 1950-1990.[49] More generally, Anne Joseph O'Connell also found that the volume of agency notice-and-comment rulemaking remains significant, and thus does not appear to be so costly that it is no longer a viable option for agencies.[50]

These studies complicate and may undermine the view that agencies have increasingly relied on separately issued guidance documents in response to the greater demands on, and costs of, notice-and-comment rulemaking. But these studies do not address the extent to which the agency preambles have been devoted to justifying the legal

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[46] *See, e.g.*, Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1316-17(1992) (arguing that with the increased cost of notice-and-comment rulemaking, agencies are increasingly willing to rely on forms of nonlegislative rules, such as interpretative rules and general statements of policy to implement their statutes); Pierce, *Seven Ways*, *supra* note 41, at 86 (same).

[47] Connor Raso did not find evidence that agencies issued guidance documents more often as presidential terms waned, nor more frequently during periods of divided government. *See* Connor N. Raso, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 806-07 (2010).

[48] *See* Raso, *supra* note 47, at 813-14 (Table 3 showing that the ratio of significant guidance documents to significant legislative rules ranges from .00 and .01 (Defense and Energy) to .31 and .35 (Education and Homeland Security)).

[49] Jason Webb Yackee & Susan Webb Yackee, *Testing the Ossification Thesis: An Empirical Examination of Federal Regulatory Volume and Speed*, 1950-1990, 80 GEO. WASH. L. REV. 1414, 1461 (2012). The Yackees' article includes interim final rules and guidance documents in a category on "no-comment regulations," drawn from searches of the *Federal Register*. With regard to guidance published in the Federal Register, this methodological choice means that their findings of no increased reliance on guidance is very conservative because they are counting interim final rules in this category. However, their study does not capture guidance that is not published in the *Federal Register*, so may also understate agency reliance on it.

[50] *See* Anne Joseph O'Connell, *Political Cycles of Rulemaking: An Empirical Portrait of the Modern Administrative State*, 94 VA. L. REV. 889, 936 (2008) (suggesting that volume of agency rulemaking shows it is not ossified). Interestingly, Anne Joseph O'Connell's study reveals that agencies have increased issuance of direct final rules and interim final rules. *See id.* Both direct final rules and interim final rules include statements equivalent to statements of basis and purpose, but they do not undergo a pre-publication comment period. NAT'L ARCHIVES & RECORDS ADMIN., FEDERAL REGISTER DRAFTING DOCUMENT HANDBOOK, 2-6 to 2-8 (1998) (noting that direct final rules and interim final rules should include preambles explaining the rule's purpose and grounds). Agencies' increased reliance on these forms suggests that at least the "notice-and-comment rulemaking has significant costs that the agencies want to avoid." Joseph O'Connell, *supra*, at 936.

sufficiency of the regulations, as opposed to a guidance function. The increased legal demands saddled upon the agency's preamble have all been directed toward legal sufficiency or analysis requirements, not their guidance function.[51] To the extent those increased justificatory and analysis requirements have had an effect on agency's activities in rulemaking—and the lengthening of agency preambles is a good indication that they have an effect—they have augmented the prominence of the justificatory role of the preamble. Thus, while it may not be the case that agencies are generally resorting to guidance documents as opposed to engaging in notice-and-comment rulemaking, the demands on their preambles have all required more justificatory analysis and explanation, remaining silent on the guidance function of these documents. In the same vein, even as policymakers and commentators have devoted more attention to agencies' use of guidance, that attention has been almost exclusively directed to separately issued guidance, not guidance within rulemaking documents. We need a better understanding of the guidance function these documents do—and must—serve.

III. The Law Governing Contemporaneous Guidance

Assessment of best practices for providing guidance in rulemakings—that is, best practice for contemporaneous guidance—requires understanding the legal regime and constraints that apply to providing guidance in regulatory preambles, the regulatory text (including any appendices), or in separately issued documents. Despite the ubiquity of contemporaneous guidance,[52] there are few, if any, resources that draw together the legal regime applicable to contemporaneous guidance. From the perspective of the agency and the public, there are a host of questions about how the general law of guidance applies to contemporaneous guidance, including:

- What, if any, process requirements apply to issuing contemporaneous guidance?
- What, if any, process requirements apply to revising contemporaneous guidance?
- When is contemporaneous guidance subject to OIRA review?
- What, if any, guidance must be included in a regulatory preamble or regulatory text, or separately issued document?

[51] *See, e.g.*, Unfunded Mandates Reform Act, 2 U.S.C. § 1523(a) (2006); Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. § 609, Pub. L. No. 104-121, 110 Stat. 857 (1996); Regulatory Flexibility Act, 44 U.S.C. §§ 301-612 (2006); Congressional Review Act, 5 U.S.C §§ 801-08 (2006); Paperwork Reduction Act, 44 U.S.C. §§ 3501-20 (2006); 44 U.S.C. § 3504(c) (2006).

[52] *See infra* Part IV.

- What, if any, guidance may not be included in a regulatory preamble or regulatory text?
- What forms of contemporaneous guidance are reviewable?
- What standards of judicial review apply?

This Part addresses these questions, and then provides a summary of the answers in Table 1.[53]

A. Process Requirements for Issuing Contemporaneous Guidance

One of the distinctive features of separately issued guidance documents is that they are exempt from the requirements of notice-and-comment under APA § 553(b)(A).[54] But this does not mean that there are no applicable procedural requirements. The APA requires that interpretive rules and general statements of policy be published in the *Federal Register*,[55] and that other forms of guidance be publically available.[56] Preambles and regulatory text obviously must meet that publication requirement.

The more involved and less explored process issue for contemporaneous guidance arises from those agencies covered by *OMB's Good Guidance Bulletin*.[57] As noted at the outset, this Bulletin defines "guidance documents" to exclude regulatory actions,[58] so it would not apply to any guidance the agency provided in the text of its regulations. But under the definition in the Bulletin, agency preambles (as well as separately issued documents) could qualify as guidance documents within the Bulletin because they may be statements of "general applicability and future effect . . . that set[] forth a policy on a . . . regulatory issue or interpretation of a . . . regulatory issue."[59] Likewise, statements in an agency preamble could also constitute "significant guidance" which includes guidance leading to an annual effect on the economy of more than $100 million, creating serious inconsistencies with another agency's actions or planned actions, altering budget impacts

[53] *See infra* Section III(H).
[54] 5 U.S.C. § 553(b)(A) (2006).
[55] 5 U.S.C. § 552(a)(1)(D) (2006).
[56] 5 U.S.C. § 552(a)(2)(B) (2006).
[57] *OMB's Good Guidance Bulletin*, *supra* note 1. The Bulletin applies only to executive agencies. *See id.* § I.2 (defining "agency" as agencies other than those considered to be independent regulatory agencies under 44 U.S.C. § 3205(5)).
[58] *Id*. § I.3 ("The term 'guidance document' means an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended by, section 3(g)), that sets forth a policy on statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.").
[59] *Id*.

on entitlements, or raising novel legal issues arising out of legal requirements or the president's priorities or Executive Order 12,866.[60]

Accordingly, for executive agencies, to the extent any statements in an agency preamble as well as those in separately issued documents would be considered "significant guidance documents" or even "economically significant guidance documents" under the Bulletin, the agency would have to comply with the procedural requirements the Bulletin imposes.[61] Most interesting for their application to preambles are the requirement that: (1) there be a designation of the statement as "guidance" (or its equivalent),[62] (2) the agency maintain on its web site a list of significant guidance documents,[63] and (3) the agency structure a means for the public to submit comments on significant guidance documents.[64] While many agencies provide extensive guidance about the meaning and operation of their regulations in their preambles, few agencies appear to treat their preambles as subject to the procedural requirements of *OMB's Good Guidance Bulletin* which, by its own terms, could apply to guidance provided in preambles.

Consider in particular *OMB's Good Guidance Bulletin*'s requirement that each agency maintain on its web site a list of its current significant guidance documents in effect, including a link to the document.[65] Based on a review of the web sites of the 21 executive branch agencies that have issued an economically significant regulation in the last 15 years,[66] only the Department of Transportation's web site on guidance mentions preambles as a source of guidance.[67]

In sum, while guidance provided in agency preambles or in regulatory text clearly meet the APA's publication requirements, these same statements, if their effects are significant, could require compliance with *OMB's Good Guidance Bulletin*. That would require the agency to be conscientious about how it designated those guidance portions, to

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[60] *Id*. § I.4(a)(i)-(iv).
[61] *Id*. § II.2-3 (outlining basis procedures for significant guidance). The Bulletin's imposition of procedural requirements for issuing guidance builds upon ACUS Recommendation 92-2 on Agency Policy Statements. That recommendation urged agencies to provide procedures to challenge the legality and wisdom of the statements prior to these policies being applied. *See* Admin. Conf. of the United States, Agency Policy Statements, Recommendation 92-2, ¶ II(B), 57 Fed. Reg. 30,103 (June 18, 1992).
[62] *Id*. § II.2 (setting out requirement elements for significant guidance).
[63] *Id*. § III.1 (providing for Web posting of significant guidance).
[64] *Id*. § III.2 (setting forth requirements for public to submit comments and complaints about its guidance).
[65] *Id*. § III.1.
[66] This list of agencies is drawn from DAVID E. LEWIS & JENNIFER L. SELIN, SOURCEBOOK OF UNITED STATES EXECUTIVE AGENCIES 132 (Table 20) (December 2012 First Edition). It includes: USDA, DOC, DOD, DOED, HHS, DHS, HUD, DOI, DOJ, DOL, STAT, DOT, DTRS, DVA, EPA, EEOC, OMB, OPM, RRB, SBA, SSA.
[67] The web sites on guidance for the agencies noted did not include mention of preambles or a rule's statement of basis and purpose, except for DOT (websites on guidance visited March 2014).

post or mention preambles alongside other significant guidance on their web sites, and even to provide an opportunity to comment on the significant guidance in preambles, among other requirements.

B. Process Requirements for Revising Contemporaneous Guidance: The Impact of *Alaska Professional Hunters*

The process requirements that apply to an agency decision to revise contemporaneously issued guidance are even clearer than those that apply to issuing contemporaneous guidance. Clearly guidance issued as part of a regulatory text can only be revised through a new notice-and-comment proceeding. Based on the rule adopted by the D.C. Circuit in *Alaska Prof'l Hunters Ass'n v. FAA*[68] and *Paralyzed Veterans of America v. D.C. Arena*,[69] in some cases, agencies must also proceed through notice-and-comment to revise guidance provided in their preambles.

The "*Alaska Hunters*" rule, also known as the "one-bite" rule,[70] states that "[w]hen an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment."[71] As the D.C. Circuit recently clarified, in *Mortgage Bankers Ass'n v. Harris*,[72] this rule involves two basic inquiries: whether the interpretation is definitive ("definitiveness"), and whether there has been a significant change in the interpretation ("significant change"), but does not require substantial and justified reliance on the prior interpretation.[73]

In *Paralyzed Veterans*, the D.C. Circuit characterized a change in an interpretation of a rule as an "amendment" to a regulation.[74] The court then turned to APA § 551(5), which defines "rulemaking" as including "formulating, amending, or repealing a rule."[75] On this basis, the court concluded that amendments in the form of changes to interpretations must go through notice-and-comment.[76] As commentators have pointed out,

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[68] 177 F.3d 1030, 1035-36 (D.C. Cir. 1999).
[69] 117 F.3d 579, 588 (D.C. Cir. 1997).
[70] Stack, *supra* note 29, at 415–16.
[71] 177 F.3d at 1034.
[72] 720 F.3d 966 (D.C. Cir. 2013), *petition for cert. filed*, Nos. 13-1041, 13A636 (Feb 28, 2014).
[73] *Id*. at 969; Matthew P. Downer, Note, *Tentative Interpretations: The Abracadabra of Administrative Rulemaking and the End of Alaska Hunters*, 67 VAND. L. REV. (forthcoming 2014) (exploring distinction between definitive and tentative interpretations).
[74] *See Paralyzed Veterans*, 117 F.3d at 586.
[75] *Id*.
[76] *Id*.; 5 U.S.C. 551(5) (2012).

the *Paralyzed Veterans* court neglected to consider that § 553, which sets forth the requirements for notice-and-comment rulemaking, specifically exempts "interpretative rules" from notice-and-comment.[77]

Alaska Hunters formalized this application into a rule.[78] At issue in *Alaska Hunters* was a thirty-year-old practice of the Federal Aviation Administration's Alaska regional office that uniformly advised hunting and fishing guides flying clients on Alaskan hunting tours that they were not considered "commercial operators," a treatment that resulted in exempting these businesses from some FAA regulations.[79] In 1997, FAA officials in Washington, D.C. published a "Notice to Operators" announcing that it would interpret these hunting businesses as "commercial operators" subject to commercial operator regulations going forward.[80] Relying on *Paralyzed Veterans*, the *Alaska Hunters* court held that the "Notice to Operators" was procedurally invalid because it effectively amended a regulation by changing a definitive interpretation without notice-and-comment.[81] The prior interpretation, the court noted, had become "an authoritative departmental interpretation, an administrative common law."[82] In subsequent decisions, the D.C. Circuit has narrowed the scope of this rule somewhat, holding that when an administrative interpretation includes conditional language (e.g., "may use," "can be used") or did not establish an "express, direct, and uniform interpretation,"[83] it is not definitive. While roundly criticized by commentators as inconsistent with the APA § 553,[84] the D.C. Circuit and several other Circuits continue to apply this doctrine.[85]

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[77] Jon Connolly, Note, *Alaska Hunters and the D.C. Circuit: A Defense of Flexible Interpretive Rulemaking*, 101 COLUM. L. REV. 155, 160, 165 (2001).

[78] Alaska Prof'l Hunters Ass'n, 177 F.3d at 1034 (citing *Paralyzed Veterans*, 117 F.3d at 586) ("'Rule making,' as defined in the APA, includes not only the agency's process of formulating a rule, but also the agency's process of modifying a rule.").

[79] *Id*. at 1031-32.

[80] *Id*. at 1033.

[81] *Id*. at 1034.

[82] *Id*. at 1035.

[83] MetWest Inc. v. Sec'y of Labor, 560 F.3d 506, 509 (D.C. Cir. 2009) (conditional statement, "circumstances may exist," in guidance does not establish a definitive agency interpretation); Darrell Andrews Trucking, Inc. v. Fed. Motor Carrier Safety Admin., 296 F.3d 1120, 1126 (D.C. Cir. 2002) (presence of language "can be used" or "could be used" rendered guidance ambiguous and thus did mark a definitive interpretation); Ass'n of Am. R.R.s v. Dep't of Transp., 198 F.3d 944, 949 (D.C. Cir. 1999) (agency interpretations not sufficiently authoritative or uniform).

[84] Richard W. Murphy, *Hunters for Administrative Common Law*, 58 ADMIN. L. REV. 917, 918 (2006) ("Academic commentary on [the Alaska Hunters doctrine] has been scathing."); *see also* William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321, 1329 (2001) (criticizing the D.C. Circuit's reasoning in Alaska Hunters); Pierce, *Seven Ways*, *supra* note 41, at 566 (same); Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 846 (2001) (same); Brian J. Shearer, Comment, *Outfoxing Alaska Hunters: How Arbitrary and Capricious Review of Changing Regulatory Interpretations Can More Efficiently Police Agency Discretion*, 62 AM. U. L. REV. 167, 171 (2012) (same); Connolly, supra note 77, at 157 (same).

The *Alaska Hunters* rule has clear implications for preambles. It seems clear that guidance provided in a preamble to a regulation could be definitive under *Alaska Hunters*. Guidance provided in a preamble is clearly authoritative; it is the agency as an institution that issues it. So long as it was not conditional or ambiguous, it would qualify as a definitive interpretation. As a result, under *Alaska Hunters*, for the agency to significantly change its definitive guidance provided in a preamble would require the agency to undergo a new notice-and-comment proceeding. The idea that a notice-and-comment proceeding is required to change guidance given in a preamble to a regulation may strike many as an odd result in part because it appears to blur the distinction between rule and preamble.

That blurring follows from *Alaska Hunters*, but also has an important implication for agencies: For definitive guidance, there may be less procedural difference that would initially appear between providing that guidance in the preamble or in the regulatory text. Both can be changed only through notice-and-comment. So the difference in procedural requirements is only a difference in the processes that govern their issuance: Regulatory text is subject to notice-and-comment under the APA, whereas guidance in a preamble is at most subject to the notice obligations imposed by *OMB's Good Guidance Bulletin* (which in turn involves notice and comment for economically significant guidance). The same analysis applies to authoritative, separately issued guidance documents.

C. When Is Contemporaneous Guidance Subject to OIRA Review?

For agencies that are not independent regulatory agencies,[86] preambles to significant final rules, the text of those rules, as well as significant guidance documents are all subject to some oversight by the Office of Information and Regulatory Affairs under Executive Order 12,866.[87]

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[85] *See* Mortg. Bankers Ass'n v. Harris, 720 F.3d 966 (D.C. Cir. 2013) (reaffirming the *Alaska Hunters* doctrine). The Third, Fifth and Sixth Circuits have adopted the *Alaska Hunters* doctrine. *See* SBC Inc. v. FCC, 414 F.3d 486, 498 (3d Cir. 2005); Dismas Charities, Inc. v. U.S. Dept. of Justice, 401 F.3d 666, 682 (6th Cir. 2005); Shell Offshore Inc. v. Babbitt, 238 F.3d 622, 629 (5th Cir. 2001). In contrast, the First, Seventh, and Ninth Circuits have rejected the Alaska Hunters doctrine. *See* Abraham Lincoln Mem'l Hosp. v. Sebelius, 698 F.3d 536 (7th Cir. 2012); Erringer v. Thompson, 371 F.3d 625 (9th Cir. 2004); Warder v. Shalala, 149 F.3d 73 (1st Cir. 1998). The Tenth Circuit appeared to criticize the *Alaska Hunters* decision, but did not either formally adopt or reject it. *See* United States v. Magnesium Corp. of Am., 616 F.3d 1129 (10th Cir. 2010).

[86] Exec. Order. No. 12,866 § 3(b), 3 C.F.R 638 (1994) (defining agencies, unless otherwise noted, as excluding independent regulatory agencies as listed in 44 U.S.C. § 3502(10)).

[87] Id. at § 3(e).

Executive Order 12,866 defines regulatory actions as "any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation . . . advanced notices of proposed rulemaking, and notices of proposed rulemaking."[88] Preambles to final rules and regulatory text are clearly "regulatory actions." As such, under the Executive Order's Centralized Review provisions, for regulations that are "significant,"[89] covered agencies must provide the text of the preamble and the regulatory text to OIRA for review.[90]

In addition, "significant" guidance documents are also subject to OIRA review. While President Obama revoked President Bush's Executive Order which formally subjected guidance documents to review,[91] that did not remove significant guidance documents from OIRA review. As former OIRA Administrator Cass Sunstein reports, "Across multiple administrations, OIRA has long reviewed such [guidance] documents . . . so long as they count as 'significant.'"[92] This understanding was confirmed by then-OMB Director Peter Orzag in a March 2009 memorandum that made clear that the revocation of President Bush's Executive Order formally including guidance in regulatory review restored regulatory review to the process between 1993 and 2007.[93] "During that period," Director Orzag wrote, "OIRA reviewed all significant proposed final agency actions, including significant policy and guidance documents."[94]

D. What Contemporaneous Guidance is Required?

While there are no general legal requirements to include guidance in regulatory text,[95] there are minimum obligations for contemporaneous guidance to be included in regulatory preambles as well as in separate guidance documents called "compliance guides" for rules that have "a significant impact on a substantial number of small entities,"

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[88] *Id.*
[89] *Id*. § 3(e).
[90] *Id*. § 6(a)(3)(B).
[91] Exec. Order No. 13,497, 3 C.F.R. 218 (2010), revoking Exec. Order No. 13422, 3 C.F.R. 191 (2008) (revoked) (subjecting guidance to regulatory review).
[92] Cass R. Sunstein, The Office of Information and Regulatory Affairs: Myths and Realities, 126 HARV. L. REV. 1838, 1853 (2013).
[93] *See* Orzag Memorandum, *supra* note 2. The issuance of this memorandum, Sunstein reports, "reflects broad support for such review within the Executive Office of the President," notwithstanding the fact that guidance might strictly fit within Executive Order 12,866's definition of "regulatory action." *See* Sunstein, *supra* note 92, at 1853 n.60. For a description of the character of OIRA's review of guidance documents during that period, *see* Jennifer Nou, *Agency Self-Insulation Under Presidential Review*, 126 HARV. L. REV. 1755, 1785 (2013).
[94] *See* Orzag Memorandum, *supra* note 2.
[95] President Clinton's directive on plain language, which includes plain language in final rules, remains in effect. *See* Memorandum for the Heads of Executive Departments and Agencies on "Plain Language in Government Writing" (June 1, 1998), 63 Fed. Reg. 31,885 (June 10, 1998).

as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).[96]

1. Preambles

The near exclusive focus on the justificatory function of statements of basis and purpose in regulatory preambles also completely occludes the question of what minimum level of guidance preambles must provide. There are two legal sources that could be understood to impose a minimum guidance obligation on the agency: the requirement of APA § 553 that the agency issue a "statement of basis and purpose," as enforced by the courts, and the Regulatory Flexibility Act's requirement that agencies engaged in rulemaking under § 553 provide a "statement of the need for, and objective of, the rule."[97]

These requirements ensure that a minimum guidance function is served by the preamble. *Independent U.S. Tanker Owners Committee v. Dole*[98] provides the established formulation of the necessary requirements for an agency's statement of basis and purpose to be procedurally valid. While the statement need not "be an exhaustive, detailed account of every aspect of the rulemaking proceedings," the statement "should indicate the major issues of policy that were raised in the proceedings and explain why the agency decided to respond as it did, particularly in light of the statutory objectives that the rule must serve."[99] Under this standard, the *Independent U.S. Tankers* court concluded that the agency's statement did not explain how the rule furthered statutory objectives, and accordingly vacated the rule.[100]

Requiring this articulation in the statement of basis and purpose clearly helps a reviewing court assess whether the agency has taken a hard look at the problem in light of its statutory objectives. But it just as clearly serves a guidance function. It requires the agency to provide an independent articulation of the purpose of the rule and its place in the implementation of the statute. The fact, as *Independent Tankers* held, that issuing a statement of basis and purpose with an adequate explanation of how the rule furthers the statute's purposes is *procedurally* necessary for a notice-and-comment rulemaking[101] suggests that guidance is one of the purposes—and minimum obligations imposed on—these statements. In other words, part of what makes a statement of basis procedurally

[96] 5 U.S.C. § 601 notes, § 212 (requiring the production of compliance guides whenever the agency must produce a regulatory flexibility analysis under 5 U.S.C. § 605(b) and quoting § 605(b)).
[97] 5 U.S.C. § 604(a)(1) (2012)
[98] 809 F.2d 847 (D.C. Cir. 1987).
[99] *Id.* at 852.
[100] *Id.*
[101] *Id.*

valid is providing a minimum level of guidance that explains how the rule implements the statute's purpose. From this perspective, statement of basis and purpose that falls short of this minimum requirement does not perform its necessary guidance function of stating the rule's purposes in light of statutory objectives.[102]

The Regulatory Flexibility Act (RFA) requires that when an agency promulgates a final rule through notice-and-comment, the agency must provide a "regulatory flexibility analysis" that includes "a statement of the need for, and objectives of, the rule,"[103] published in the *Federal Register*.[104] The RFA's requirements are "[p]urely procedural" and so "requires nothing more than that the agency file a [final regulatory flexibility analysis] demonstrating a 'reasonable, good-faith effort to carry out [RFA's] mandate'."[105] Still, RFA sets out "precise, specific steps the agency must take."[106] And reviewing courts will assess whether the agency's analysis "addressed all of the legally mandated subject areas."[107] Substantial compliance is not authorized.[108] Accordingly, where an agency fails to address one of those mandated subjects, a reviewing court will remand to the agency to conduct the analysis required by RFA.[109]

While the court deferentially reviews the substance of an agency's final regulatory flexibility analysis for the purposes of assessing compliance with RFA, the fact remains that the agency must state the need for and objectives of the rule. That requirement may help to enforce discipline on the agency, requiring it to have a clearly stated objective and rationale for its rules. But the requirement of publication in the *Federal Register* also suggests that there is a minimum guidance function enforced by RFA as well.

At a minimum, both the APA and the RFA require the agency to provide a statement of the need for the rule and the rule's objectives in light of the authorizing

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[102] Direct Final Rules and Interim Final rules should also include the functional equivalent of a preamble, *see* FEDERAL REGISTER DRAFTING DOCUMENT HANDBOOK, *supra* note 50, at 2-6 to 2-8 (1998) (noting that direct final rules and interim final rules should include preambles explaining the rule's purpose and grounds); Ronald M. Levin, *Direct Final Rulemaking*, 64 GEO. WASH. L. REV. 1, 16-18 (1995) (noting direct final rules and interim final rules include functional equivalent of statement of basis and purpose); FEDERAL REGISTER DRAFTING DOCUMENT HANDBOOK, *supra* note 50, at 2-6 to 2-8 (1998) (noting that direct final rules and interim final rules should include preambles explaining the rule's purpose and grounds), which could also be viewed as having this same minimum guidance function.
[103] 5 U.S.C. § 604 (2012).
[104] 5 U.S.C. § 604(a)(6)(b) (2012).
[105] United States Cellular Corp. v. FCC, 254 F.3d 78, 88 (D.C. Cir. 2001).
[106] Nat'l Tel. Co-op. Ass'n v. FCC, 563 F.3d 536, 539-40 (D.C. Cir. 2009).
[107] *Id.*
[108] Aeronautical Repair Station Ass'n v. FAA, 494 F.3d 161, 178 (D.C. Cir. 2007) (remanding to FAA inadequate FRFA but not staying effect of rule).
[109] *See id.* at 177-78.

statute's aims. Preambles that do not include those statements do not satisfy their guidance function and thus should be procedurally invalid.

2. Separately Issued Documents

Section 212 of SBREFA requires agencies to publish a "small entity compliance guide" at the same time as the publication of the final rule (or as soon as possible thereafter) and no later than when the rule becomes effective.[110] These guides shall "explain the actions a small entity is required to take to comply with a rule,"[111] which "shall include a description of actions needed to meet the requirements of a rule, to enable a small entity to know when such requirements are met,"[112] and include descriptions of procedures that "may assist a small entity in meeting" the rule's requirements.[113] These guides must be written "using sufficiently plain language likely to be understood by the affected small entities."[114] These compliance guides must be easily accessible on the web site of the agency, and distributed to known industry contacts, such as affected associations.[115]

E. What May Not Be Included in Contemporaneous Guidance?

1. Restrictions on Guidance in the Code of Federal Regulations

Only those rules that have "general applicability and legal effect" may be codified in the regulatory text of the Code of Federal Regulations.[116] The regulations implementing this statutory requirement define documents have "general applicability and legal effect" to mean "any document issued under proper authority prescribing a penalty or course of conduct, conferring a right, privilege, authority, or immunity, or imposing an obligation."[117] Thus, the codified text of the CFR may not include guidance, though

[110] Small Business Regulatory Enforcement Fairness Act, Pub. L. No. 104-121, § 212(a), 110 Stat. 873, codified at 5 U.S.C. § 601 nt. (2012).
[111] *Id*. § 212(a)(4).
[112] *Id*. § 212(a)(4)(B)(i).
[113] *Id*. § 212(a)(4)(B)(ii).
[114] *Id*. § 212(a)(5). The Plain Writing Act of 2010, Pub. L. No. 111-274, 124 Stat. 2861 (Oct. 31, 2010) also imposes a plain writing requirement on documents that "explain[] to the public how to comply with a requirement the Federal Government administers or enforces." *Id*. § 3.
[115] *Id*. § 212(a)(2).
[116] 44 U.S.C. § 1510(a); 1 C.F.R. 8.1 (the Code of Federal Regulations shall contain each Federal regulation of general applicability and legal effect); *see also* Wilderness Soc. v. Norton, 434 F.2d 584, 596 (D.C. Cir. 2006) (the CFR may contain only documents having general applicability and legal effect).
[117] 1 C.F.R. § 1.1.

agencies may include notes and examples with their codified text, or guidance in appendices to codified text.[118]

2. Preamble-Specific Restrictions

a. Restriction on Preemption Statements. Perhaps the most straightforward and recent restriction on the guidance statements that may be made in preambles is President Obama's Memorandum for the Heads of Executive Departments and Agencies on Preemption.[119] This Memorandum directs executive agencies not to include statements in regulatory preambles to the effect that the agency intends the regulation to preempt state law unless preemption provisions are also codified in the regulation's text.[120]

b. Statements Without Corresponding Rules. There is some authority supporting the principle that statements in the preamble to a final rule that do not pertain to any aspect of the rules adopted are nullities in the sense that they are not validity issued even as explanatory statements. This principle arose in a D.C. Circuit decision's review of a drafting error in an EPA rule. The D.C. Circuit was confronted with a statement in the preamble referring to EPA's "final rule concerning high wind events" which states that "ambient particulate matter concentrations due to dust being raised by unusually high winds will be treated as due to uncontrollable natural events."[121] The final regulatory text, however, did not make any reference to high wind events or "ambient particulate matter concentrations,"[122] an oversight that EPA characterized as a drafting error. The court held that in view of this error, "the high winds event section of the preamble is a legal nullity."[123] While it is unclear how broad this principle is, at a minimum, the principle appear to apply to statements that refer to rules that do not exist. Such statements are nullities in the sense not being validly issued. It would seem a reasonable extension of this principle to apply it to statements exceed the scope of the rules adopted, for instance, by suggesting compliance obligations that extend beyond the scope of the rules.

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[118] FEDERAL REGISTER DRAFTING DOCUMENT HANDBOOK, *supra* note 50, at 7-9 (discussing use of appendices to clarify but not to impose substantive obligations).
[119] Preemption: Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24,693, 24,693-94 (May 20, 2009), available at http://www.gpo.gov/fdsys/pkg/FR-2009-05-22/pdf/E9-12250.pdf#page=1.
[120] *Id.* at ¶ 1.
[121] Natural Res. Def. Council v. EPA, 559 F.3d 561, 565 (D.C. Cir. 2009) (quoting the preamble).
[122] *Id.*
[123] *Id.*

2. Restrictions Applicable to Preambles and Separately Issued Documents

a. Subterfuge Legislative Rules. Neither a preamble nor a separately issued guidance document may contain a legislative rule. As a matter of blackletter law, under APA § 553, a "legislative" rule must be subject to notice-and-comment whereas interpretative statements and general statements of policy are not.[124] Thus, if a preamble or guidance document includes a statement that is a legislative rule, the rule is procedurally invalid under section 553. While the differences in legal effect and procedural requirements for legislative and nonlegislative rules are straightforward, distinguishing between legislative and nonlegislative rules is a notoriously difficult issue.[125] Courts rely on a collection of doctrinal factors, including the "agency's label,"[126] the practical impact on those covered by the rule,[127] and a legal effect test,[128] which looks to whether the rule imposes legal rights or obligations.[129] Numerous formulations of these and other factors are found in the courts of appeals.[130]

With regard to statements in preambles challenged as legislative rules, courts must wade into those same muddy waters. Interestingly, despite numerous challenges to language in preambles as improper legislative rules, courts have consistently held that statements in preambles are interpretive rules or general statements of policy, and thus procedurally valid.[131] Because of the blurry lines of the distinction between legislative and

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[124] Administrative Procedure Act of 1946 § 553(b)(3)(A), 5 U.S.C. § 553(b)(3)(A) (2006). "Legislative" or "substantive" rules are those that "'grant rights, impose obligations, or produce other significant effects on private interests,' or which 'effect a change in existing law or policy.'" Am. Tort Reform Ass'n v. OHSA, 738 F.3d 387, 395 (D.C. Cir. 2013) (citations omitted).

[125] *See, e.g.*, David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 278 (2010) (suggesting there is perhaps "no more vexing conundrum in the field of administrative law than the problem of defining a workable distinction between legislative and nonlegislative rules.").

[126] *See, e.g.*, Warshauer v. Solis, 577 F.3d 1330, 1337 (11th Cir. 2009) (the agency's "characterization of the rule is relevant").

[127] Cent. Tex. Tel. Coop., Inc. v. FCC, 402 F.3d 205, 214 (D.C. Cir. 2005) (noting that court had used a substantial impact test); *see also* William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321, 1325 (2001) (noting strain of cases looking to substantive impact on the regulated).

[128] *See, e.g.*, Miller v. Cal. Speedway Corp., 536 F.3d 1020, 1033 (9th Cir. 2008) (legislative rules "create rights, impose obligations, or effect a change in the law").

[129] Troy Corp. v. Browner, 120 F.3d 277, 287 (D.C. Cir. 1997).

[130] *See, e.g.*, Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106 (D.C. Cir. 1993) (listing the following factors: "(1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule.").

[131] *See, e.g.*, Troy Corp. v. Browner, 120 F.3d 277, 287 (D.C. Cir. 1997) (EPA's premabular statement "merely informed the public that the agency would exercise its discretion by considering exposure only for low toxicity chemicals" and thus was a general policy statement); Fertilizer Institute v. EPA, 935 F.2d 1303, 1308-09 (D.C. Cir. 1991) (holding that EPA's rule in its preamble was interpretive because it represents "the

nonlegislative rules, it is difficult to tell whether this consistent practice is a result of the caution exercised by agencies in their preambles to avoid any mandatory or binding statements or simply a more relaxed judicial review of statements in preambles than in separately issued guidance documents. Given that courts frequently invalidate separately issued guidance documents, the trend is notable.

b. Consistency with Regulations and Statutes. Most obviously, statements in preambles (as well as separately issued documents) must be consistent with the regulations they explain and the statutes they implement. Both of these points are illustrated in *Cuomo v. Clearing House Association, LLC.*[132] There, the Court held that the interpretation of a regulation in the Comptroller of the Currency's statement of basis and purpose was inconsistent with the regulation's text as well as the underlying statute, and therefore invalid. "This passage in the statement of basis and purpose," the Court commented, "resting upon neither the text of the regulation nor the text of the statute, attempts to do what Congress declined to do: exempt national banks from all state banking laws, or at least state enforcement of those laws."[133]

F. Reviewability of Contemporaneous Guidance

Contemporaneous guidance is reviewable in court if it constitutes "final agency action"[134] and satisfies the requirements of ripeness.[135] These requirements would generally be satisfied for guidance included in the codified text of a regulation or its appendix, and so the reviewability of those forms of guidance does not merit discussion. Likewise, the reviewability of separately issued guidance is solely a matter of application

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agency's attempt to interpret the meaning of a statutory provision"); Barrick Goldstrike Mines, Inc. v. Whitman, 260 F. Supp. 2d 28, 38 (D.D.C. 2003) ("In this case, the interpretation [contained within the preamble] . . . is within the scope of the regulation"); Bd. of Trustees of Knox Cnty. Hosp. v. Shalala, 959 F. Supp. 1026, 1031 (S. D. Ind. 1997) ("Rather than create or destroy substantive rights, the [preambular] policy simply clarifies what the Secretary believes the regulation means and explains how the Agency will apply it."); OSG Bulk Ships v. United States, 921 F. Supp. 812, 824 n.11 (D.D.C. 1996) (explaining that an interpretation within the preamble does not transform the preamble into a legislative rule); Comité de Apoyo a los Trabajadores Agrícolas v. Solis, No. 09-240, 2010 U.S. Dist. LEXIS 90155 at 47 (E.D. Pa. Aug. 30, 2010) (holding that the preambular language was an interpretation because the language was "very closely tied" to the definition included in the regulation and "expressly purports to be an interpretation of that definition").

[132] 557 U.S. 519, 129 S. Ct. 2710 (2009).

[133] *Id.* at 2720; *see also* Home Concrete & Supply, LLC v. United States, 634 F.3d 249, 256–57 (4th Cir. 2011) (rejecting the IRS's interpretation contained in the preamble to a regulation because it was "contrary to the clearly and unambiguously expressed intent of Congress and must fail"); *Barrick*, 260 F. Supp. 2d at 36 ("Because the preamble to the 1988 rulemaking is inconsistent with the plain language of the regulation, *see* Auer, 519 U.S. at 461, it is invalid. Accordingly, subject to the concentrations of toxic chemicals it contains, Barrick's waste rock may be eligible for the de minimis exemption.").

[134] 5 U.S.C. § 704 (providing that final agency action is reviewable)

[135] There are, of course, elements to the availability of review, including standing, but finality and ripeness are the post germane to assessing reviewability of contemporaneous guidance.

of general principles of finality and ripeness, for which there are existing treatments.[136] But what about guidance provided in preambles? Is this form of guidance reviewable?

The short answer is that guidance in preambles has been found to be both final and ripe, and thus subject to review. Perhaps the most prominent example of a decision concluding that language in a preamble is reviewable is the Supreme Court's decision in *Whitman v. American Trucking Associations*.[137] While the statements at issue concerned the agency's interpretation of a statute, not its own regulations, the decision reveals clearly that statements in regulatory preambles, just like other forms of guidance, may be reviewable if they are final and ripe.[138] After soliciting comment on an interim implementation policy for national ambient air quality standards (NAAQS) under the Clean Air Act, the EPA published an explanatory preamble to its final ozone NAAQS, including a sectioned entitled "Final decision on preliminary standard." In that section of the preamble, the EPA stated that it had reconsidered its proposed interpretation and "now believes that the Act should be interpreted such that the provisions of subpart 2 continue to apply" to certain areas of the country that fall below ambient air quality standards. "As a consequence," the preamble stated "the provisions of subpart 2 . . . will continue to apply as a matter of law for so long as an area is not attaining [requisite air quality standard]."[139]

In *Whitman*, the Supreme Court had no difficulty concluding that these statements were reviewable. As to finality, the Court concluded that these statements marked "the consummation of the agency's decisionmaking process," a decision bolstered by the fact that in subsequent rulemakings, the EPA had denied requests to reconsider the issue, explaining "to disappointed commentators that it's earlier decision was conclusive."[140] As to ripeness, under the standard of *Abbott Laboratories v. Gardner* looking to the "fitness of the issues for judicial decision" and the "hardship to the parties of withholding court consideration,"[141] the Court concluded that the issue of statutory interpretation presented and the hardship on states that would be imposed justified review under the Clean Air Act's special authorization for preenforcement review,[142] and declined to opine on whether the statement would be ripe in a case brought under APA § 704.[143]

The standard for final agency action under APA § 704 is well established: "A final agency action is one that marks the consummation of the agency's decisionmaking process

[136] *See, e.g.*, Lubbers, *supra* note 30, at 398-402 (discussing whether guidance is "final" agency action).
[137] 531 U.S. 457 (2001).
[138] *See id.* at 478.
[139] 62 Fed. Reg. 38873 (1997), discussed in *Whitman*, 531 U.S. at 478.
[140] 531 U.S. at 478-79.
[141] *Id.* at 479 (quoting Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967)).
[142] 531 U.S. at 479.
[143] *Id.* at 479.

and that establishes rights and obligations or creates binding legal consequences."[144] Applying this standard to statements in preambles, the D.C. Circuit has commented that "[w]hile preamble statements may in some unique cases constitute binding, final agency action susceptible to judicial review, . . . that is not the norm."[145] Still, the D.C. Circuit has held that statements in preambles are final and ripe for review on numerous occasions, including with regard to statements of regulatory interpretation.[146] A critical factor in making this determination is the language of the preamble. On the one hand, language that is not definitive (such as "may," "might" and "could"),[147] hypothetical or non-specific,[148] conjectural,[149] or characterizes the views as preliminary,[150] or promises future binding action,[151] all counsel against reviewability. On the other hand, language which is clear, not conjectural, and not qualified, makes it "fair to infer that [the agency] intended the statements to create binding legal consequences."[152]

Thus, the appearance of guidance within a preamble does not bar review.[153] Rather, the reviewability of guidance within a preamble, like the reviewability of guidance generally, depends upon the finality and ripeness analysis, which for these purposes often "converge."[154] Ultimately, then, it is the content of the guidance, not its regulatory location, that determines its reviewability.

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[144] Natural Res. Def. Council v. EPA, 559 F.3d 561, 564 (D.C. Cir. 2009) (citing Bennett v. Spear, 520 U.S. 154, 177-78 (1997)).

[145] *Id.* (citing Kennecott Utah Copper Corp. v. Department of Interior, 88 F.3d 1191, 1222-23 (D.C. Cir. 1996); *see also* Natural Res. Def. Council v. EPA, 706 F.3d 428, 432 (D.C. Cir. 2013) (affirming same). For decisions denying review of statements in preambles on finality or ripeness grounds, see, e.g., Nat'l Envtl. Dev. Ass'ns. Clean Air Project v. EPA, 686 F.3d 803, 808-09 (D.C. Cir. 2012) (preamble not final); Natural Res. Def. Council v. EPA, 559 F.3d 561, 565 (D.C. Cir. 2009) (preamble not ripe); Clean Air Implementation Project v. EPA, 150 F.3d 1200, 1208 (D.C. Cir. 1998) (preamble not final nor ripe); *Kennecott Utah Copper Corp.*, 88 F.3d at 1222-23 (extensive discussion of preamble not being final nor ripe); Florida Power & Light Co. v. EPA, 145 F.3d 1414, 1420 (D.C. Cir. 1998) (preamble neither final nor ripe).

[146] *See, e.g.*, Natural Res. Def. Council v. EPA, 571 F.3d 1245, 1252 n.2 (D.C. Cir. 2009) (holding that statements in EPA's preamble final because they represented a consummation of the agency's process, have binding consequences); La. Envtl. Action Network v. EPA, 172F.3d 65, 69 (D.C. Cir. 1999) (holding language in preamble final under RCRA, 42 U.S.C. § 6976(a)(1)); Chem. Waste Mgmt. v. EPA, 869 F.2d 1526, 1533 (D.C. Cir. 1989) (holding that regulatory interpretation in preamble was final); see also Cent. & Sw. Servs. v. EPA, 220 F.3d 683, 689 n.2 (5th Cir. 2000) (concluding EPA preamble interpreting a statute was final action and ripe); Select Specialty Hosp.-Akron, LLC v. Sebelius, 820 F. Supp. 2d 13, 26 (D.D.C. 2011) (preamble binding and reviewable).

[147] *Kennecott Utah Copper*, 88 F.3d at 1222.

[148] *Id.* at 1223.

[149] *Nat'l Envtl. Dev.*, 686 F.3d at 808.

[150] *Natural Res. Def. Council*, 706 F.3d at 433.

[151] Am. Petroleum Inst. v. EPA, 684 F.3d 1342, 1354 (D.C. Cir. 2012).

[152] Natural. Res. Def. Council, 571 F.3d at 1252 n.2.

[153] *Kennecott Utah Copper*, 88 F.3d at 1223.

[154] *Id.*

G. Standard of Judicial Review

For many years, there was little movement in the judicial doctrine first associated with *Bowles v. Seminole Rock & Sand Co.*[155] and now more consistently identified with *Auer v. Robbins*[156] that an agency's construction of its own regulation is "controlling unless 'plainly erroneous or inconsistent with the regulation.'"[157] While *Auer* still provides the general standard applicable to an agency's interpretation of its regulations—regardless of the document type in which those interpretations appear—the Supreme Court has carved out an exception for post hoc interpretive positions, and several Justices have indicated an interest in revisiting the merits of the doctrine altogether. The fact that the recent limitations on *Auer* have all been directed to *post hoc* guidance suggests that contemporaneous guidance—whether provided in a preamble, appendix, or separately issued document—has a stronger footing for maintaining *Auer* deference.

While there has been a longstanding critique of *Seminole Rock/Auer* deference,[158] current interest in the doctrine comes from the disjunction between the scope of application of *Auer* deference and *Chevron* deference created by the Supreme Court's decision in *Mead*. In *Mead*, the Court constricted the application of *Chevron* deference to statutes that grant lawmaking authority to the agency and to agency actions which exercise that authority.[159] Under *Mead*, notice-and-comment rulemaking is presumptively eligible for *Chevron* deference, whereas guidance documents are not.[160] *Mead* thus denies deference to an agency's statutory interpretation that appears in a guidance document or litigation brief, whereas a guidance document or litigation brief interpreting an agency regulation would still qualify for deference under *Auer*. This disjuncture has prompted a call for constricting the scope of application of *Auer*, so that it would apply only to those documents to which *Chevron* would apply under *Mead*, that is, those produced by relatively formal processes.[161]

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[155] 325 U.S. 410 (1945).

[156] 519 U.S. 452 (1997). While this doctrine was traditionally associated with *Seminole Rock*, but since 1997 the Supreme Court and other courts have frequently attributed it to *Auer*, *see, e.g.*, *Talk Am., Inc. v. Mich. Bell Tel. Co.*, 131 S. Ct. 2254, 2265–66 (2011) (Scalia, J., concurring) (noting that the *Seminole Rock* doctrine has recently been attributed to *Auer*), despite the fact that *Auer* involved a straightforward application of *Seminole Rock*, *see Auer*, 519 U.S. at 461 (relying on *Seminole Rock* with little ado).

[157] *Auer*, 519 U.S. at 461.

[158] John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 COLUM. L. REV. 612 (1996) (challenging *Seminole Rock* deference and proposing a model of independent judicial evaluation of regulations that would place greater reliance on agencies' explanatory statements)

[159] United States v. Mead Corp., 533 U.S. 218, 226-27 (2001).

[160] *Id.* at 229.

[161] Thomas W. Merrill & Kristin E. Hickman, *Chevron's Domain*, 89 GEO. L.J. 833, 900 (2001) ("*Seminole Rock* deference should at a minimum be subject to the same limitations that apply to the scope of *Chevron* deference."); Matthew C. Stephenson & Miri Pogoriler, *Seminole Rock's Domain*, 79 GEO. WASH. L. REV.

Despite the logic that an agency's regulatory interpretation issued informally should not receive deference if its statutory interpretation would not, the Supreme Court has generally accorded *Seminole Rock/Auer* deference to agency interpretations advanced in litigation briefs. As recently as 2011, for instance, the Court concluded twice that agency amicus briefs qualify for *Seminole Rock/Auer* deference, rejecting the argument that under *Mead* and *Christensen* they should not.[162] But, in 2012, in *Christopher v. SmithKline Beecham Corp*.[163], the Court declined to grant *Seminole Rock/Auer* deference to an agency's position taken in a litigation brief based in part on the concern that doing so would undermine fair notice of the regulation's requirements.[164] The Court reasoned that reliance on *Auer* in these circumstances would "frustrat[e] the notice and predictability purposes of rulemaking," quoting Justice Scalia's concurrence in *Talk America, Inc. v. Michigan Bell Telephone Co.*,[165] in which Justice Scalia first declared his interest in reconsidering *Auer*. The Court's explanation suggested that it viewed the distinction between guidance issued *ex ante* and *post hoc* as meaningful, at least with regard to interpretations announced in enforcement proceedings:

> It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.[166]

In March 2013, three Supreme Court Justices publically indicated an interest in reconsidering *Auer* in *Decker v. Northwest Environmental Defense Center*.[167] There, Chief Justice Roberts and Justice Alito announced they would be receptive to reconsideration of *Auer* deference in an appropriate case,[168] and Justice Scalia filed an opinion concurring in part and dissenting in part arguing for overruling *Auer* deference.[169]

1449, 1484-96 (2011) (arguing that *Mead*'s logic for constraining *Chevron*'s scope of application extends to *Seminole Rock*).

[162] *See* Pliva, Inc. v. Mensing, 131 S. Ct. 2567, 2575 n.3 (2011) (relying on brief of United States); Chase Bank USA, N.A. v. McCoy, 131 S. Ct. 871, 883–84 (2011) (rejecting argument that agency amicus brief was not entitled to deference under *Auer*, and according deference to the interpretation contained in the brief).

[163] 132 S. Ct. 2156 (2012).

[164] *See id.* at 2166–68 (concluding that "general rule" of granting *Auer* deference to interpretations in litigation briefs did not apply in these circumstances of the case in view of fair notice concerns).

[165] 131 S. Ct. 2245, 2266 (2011).

[166] *Id.*

[167] 133 S. Ct. 1326 (2013).

[168] *Id.* at 1338 (Roberts, C.J., and Alito, J., concurring) (noting that it "may be appropriate to reconsider" *Seminole Rock/Auer* in another case); *id.* at 1339, 1442 (Scalia, J., concurring in part and dissenting in part) (arguing that the Court to overturn *Seminole Rock/Auer*).

[169] *Id.*

But even if the Court were to revisit the doctrine, based on *Christopher v. SmithKline Beecham Corp.*, the Court appears to view guidance rendered contemporaneously with the issuance of the rule (or even guidance offered prior to enforcement) as standing on a different footing than post hoc interpretations produced in litigation. If this is right, then contemporaneous guidance—especially that in a preamble, regulatory text or appendix—stands in the strongest stead for deference under *Auer*: It furnishes the agency's authoritative interpretation at the time the rule become effective, and thus allows parties as much fair notice as they receive about the rule itself.

It is worth noting that an assumption underlying this discussion is that *Auer*, not *Chevron*, provides the currently governing standard of review for an agency's statements it its preamble to a final rule about the purpose and effect of its regulations. At least one court of appeals, however, has concluded that a statement's about the application of its regulations in a preamble to a final rule are entitled to receive *Chevron* deference under *Mead*.[170] If statements of this sort in a preamble receive *Chevron* deference just as statements in regulatory text does, there would be little need for courts to invoke *Auer* as a standard of review for statements about the meaning of regulations in preambles because those statements would be reviewable directly under *Chevron.*

H. Summary Table

Table 1 (below) provides a summary of the legal regime applicable to contemporary guidance addressed thus far. Readers may draw different inferences from this compilation, but one striking feature is the extent of the overlap in the requirements applicable to contemporaneous guidance, whether it appears in a preamble, regulatory text, or separately issued document. In Table 1, cells on each row that are identical are highlighted; but even where the requirements are not identical, in many cases there is significant practical overlap.

To illustrate the scope of overlap in requirements, use Table 1 to compare economically significant guidance issued in a preamble (column 1) and in a separately issued document (column 3). The requirements of issuance are the same (row 1); the requirements for revision are the same (row 2); they are both subject to OIRA review (row 3); and the same standards of judicial review (rows 6 & 7); the only difference is what content must be included or excluded.

[170] *See* Tibble v. Edison Int'l, 711 F.3d 1061, 1071 (9th Cir. 2013), *amended by* 729 F.3d 1110 (9th Cir. 2013) ("As for *Mead*'s second consideration [that the agency have exercised its authority to bind with the force of law], we do not view the fact that the interpretation appears to in a final rule's preamble as disqualifying it from *Chevron* deference.").

Table 1: Summary of Legal Regime Applicable to Contemporaneous Guidance

	Guidance in Preamble	**Guidance Published in the Code of Federal Regulations (in notes, examples, or appendices)**	**Guidance Separately Issued**
1: Process Requirements for Issuance	For covered agencies, if "significant," or "economically significant" under *OMB's Good Guidance Bulletin*, then it must comply with the GGP, including notice and comment for economically significant guidance.	Notice-and-comment required	For covered agencies, if "significant," or "economically significant" under *OMB's Good Guidance Bulletin*, then it must comply with the GGP, including notice and comment for economically significant guidance.
2: Process Requirements for Revision	If "definitive," then revision must proceed through notice-and-comment under *Alaska Prof. Hunters*.	Notice-and-comment required	If "definitive," then revision must proceed through notice-and-comment under *Alaska Prof. Hunters*.
3: Subject to OIRA Regulatory Review?	Yes, for covered agencies for all significant regulatory actions.	Yes, for covered agencies for all significant regulatory actions.	Yes, for covered agencies for all significant regulatory actions.
4: What must be included?	i. Under the APA, a statement of the purpose of the rule in light of statutory objectives, and ii. Under RFA, a statement of the need for the rule and its objectives.	No requirements other than those with a statutory basis.	Agency must publish compliance guide for rules with significant effects on small entities under SBREFA.
5: What may not be included?	i. Statements preempting state law without regulatory text that preempts. ii. Interpretations without corresponding regulatory text. iii. Statements that are binding legislative rules iv. Statements that contradict the regulatory text or statute.	The CFR text may contain only statements of general applicability and legal effect, as defined by 1 CFR 1.1.	i. Statements that are binding legislative rules, or including mandatory language ii. Statements that contradict the regulatory text or statute.

6: Is it reviewable in court?	Yes, if "final agency action" and ripe for review.	Yes, pre-enforcement review routinely available.	Yes, if "final agency action" and ripe for review.
7: What standard of review applies?	*Auer* deference (with a stronger basis than *post hoc* guidance)	*Auer* deference (with a stronger basis than *post hoc* guidance)	*Auer* deference (with a stronger basis than *post hoc* guidance)

IV. Agency Practices for Providing Contemporaneous Guidance

Given the significant overlap in the legal requirements governing contemporaneous and guidance, agencies will frequently have significant discretion as to whether to include the same statement in a preamble, regulatory text (or appendix), or in a guidance document issued alongside the rule. How do agencies make this choice? More specifically, what forms of contemporaneous guidance do agencies actually provide? This Part provides a description and illustrative compilation of the ways in which agencies use each of these forms of contemporaneous guidance. It first introduces, in Table 2, a menu of agency practices with illustrative examples. These categories are relatively straightforward; the text following Table 2 provides a narrative description of examples that fall within these categories.

The scope of federal rulemaking is vast, and it is important to note that this Report makes no claim to be a completely comprehensive identification of the ways in which agencies issue contemporary guidance. Still, the hope is that it identifies a typology or menu that captures the most significant types of use. The Report also makes no attempt to quantitatively assess the frequency with which agencies use particular forms of contemporaneous guidance, nor to provide illustrations for each agency. Rather, the effort is to identify the variety of ways in which agencies issue contemporaneous guidance in a nearly exhaustive way—isolating a menu of types of contemporaneous guidance with illustrative examples. Such a menu is sufficient to provide a means for agencies to consider their own practices in relation to those of other agencies, and also identify some problems and outliers in agency practices.

Table 2: Menu of Agency Contemporary Guidance Practices

Type	Location of Guidance	Format	Discussion
Guidance in Preamble			
	Background		

Type	Location of Guidance	Format	Discussion
	Discussion		
		Primarily Narrative Statement	Some agencies provide long narrative discussions without structuring them in accordance with the rule's structure.
		Includes Section-by-Section Analysis	In addition to general discussion, some preambles include analysis that matches the structure of rule.
		Relying Primarily on Grounds Stated in NPRM	Some preambles incorporate portions of the discussion in the NPRM.
		Purpose Stated in View of Statutory Objectives	Most preambles provide an independent assessment of the rule's purposes in relation to statutory objectives
		Purpose Statement Solely Mirroring Statutory Language (or Otherwise Inadequate)	Some agencies give this statement short shift
	Response to Comments		
		General Responses	Some preambles provide general narrative discussions of comments without much organization.
		Section-by-Section Analysis	Some preambles structure the response to comments in section-by-section.
		Question-and-Answer	Some structure preambles response to comment questions in a Q & A format
		Detailed Examples	Some preambles provide detailed examples to illustrate how the rule applies.
	Preamble as Rule		Some preambles treat the preamble and regulatory text interchangeably.

Type	Location of Guidance	Format	Discussion
Guidance included in the CFR			
	Regulatory Text		
		Example Applications	Some regulatory text includes examples to guide application.
	Appendix		
		Official Commentary in Appendix	Some appendices include an official interpretive commentary
		Examples in Appendix	Some appendices include example applications.
		Question-and-Answer Format in Appendix	Some appendices are structure with Q & A
		Technical Guidance in Appendix	Some appendices include technical guidance.
Separately Issued, Contemporaneous Guidance			
	Compliance Guides, FAQs, and Other Documents		

B. Preambles as a Vehicle for Guidance

Agencies have long treated the preambles to their regulations, which include the APA's required statement of basis and purpose, as a means of providing guidance about the meaning and application of their rules. Agencies organize their preambles—and the guidance they provide—in different formats, many of which are familiar to agency lawyers and practitioners of administrative and regulatory law.

1. Background Sections

The preamble to federal rules typically appears under the Supplemental Information heading in the *Federal Register*. Most agencies provide extensive narrative commentary on the rule, its procedural history, factual and legal grounds and aims in subsection of the Supplement Information entitled Background Discussion.[171] This section typically includes content that would constitute guidance, and agencies organize it in many different

[171] FEDERAL REGISTER DOCUMENT DRAFTING HANDBOOK, *supra* note 102, at 2-17.

ways. Agencies organize these discussions in different ways, frequently using one or more of the following formats.

a. Preamble Composed Primarily of Narrative Statement. One common format of the Background Discussion section is a narrative statement. A recent preamble produced by the Occupational Health and Safety Administration (OSHA) for a rule adopted to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) reflects this structure.[172] The preamble consists of general narrative in sections entitled, for instance, "Events Leading to the Revised Hazard Communication Standard" and "Overview of the Final Rule and Alternatives Considered."[173] In these sections, OSHA generally explained the impact and motivation for the rule, but did not organize its discussion in accordance with the particular sections of the rule.[174]

b. Section-By-Section Format. Agencies also organize background discussions of preambles in a section-by-section format. While agencies also use the section-by-section format to structure a response to comments, as discussed below, in the background discussion, the section-by-section analysis is not explicitly responding to comments.

The Consumer Protection Financial Bureau (CFPB) adopted this approach in a rule amending Regulation E, which implements the Electronic Fund Transfer Act.[175] In the preamble, there is a section-by-section analysis which is subdivided numerically and by topic with subsections such as "Section 1005.2 Definitions" and "Section 1005.3 Coverage."[176] In the coverage subsection, the agency explained changes to the regulation without referencing specific comments: "Currently, § 1005.3(a) states that Regulation E generally applies to financial institutions. Section 1005.3(a) is revised to state that the requirements of subpart B apply to remittance transfer providers. The revision reflects the fact that the scope of the Dodd-Frank Act's remittance transfer provisions is not limited to financial institutions."[177]

c. Agency Reliance on Grounds Stated in NPRM. In preambles to final rules, agencies vary as to how much they rely on grounds stated in the NPRM or other

[172] Hazard Communication, 77 Fed. Reg. 17,574, 17,574 (March 26, 2012) (to be codified at 29 C.F.R. pts. 1910, 1915, 1926).
[173] *Id.* at 17,577, 17,579, 17,693.
[174] *Id.*
[175] Electronic Fund Transfers (Regulation E), 77 Fed. Reg. 6,194, 6,194 (Feb. 7, 2012) (to be codified at 12 C.F.R. pt. 1005).
[176] *Id.* at 6,204–6,205.
[177] *Id.* at 6,205.

prior notices or treat the preamble to the final rule as a freestanding document that provides a relatively comprehensive statement of the rule's basis and purpose in the way that most judicial opinions do. Agencies frequently refer the readers to explanations, proposals, or studies published in the NPRM**.** Agencies occasionally specifically incorporate particular aspects of the legal reasoning or analysis provided in the NPRM.[178] Agencies also rely upon reasoning and discussions in the NPRM for a more comprehensive summary of the rule's basis, purposes and effects.[179] In contrast, agencies also treat the preamble as a relatively comprehensive, and stand-alone statement of the grounds of the rule, referring to the NPRM only as necessary to explain how the agency's reasoning has shifted or how the agency has responded to comments and it is explanation of the rulemaking process.

d. Purpose Statements. Agencies typically provide a statement of the purpose of the regulation in the Summary and/or in the Supplemental Information sections of their preambles to their substantive rules, that is, those that have independent legal effect. These statements vary widely in terms of their level of specificity and clarity. Many statements clearly indicate the purpose of the regulation in light of the statute's objectives, the agency's powers, and its past regulatory history.[180]

Rather than providing an independent assessment of the purpose of the rule in light of the statute, some preambles state the purpose of their regulations in terms that largely mirror statutory language. For instance, a Department of Labor rule establishing the uniform national threshold for the employment rate for veterans included a purpose statement that largely mirrored the statutory language requiring the agency to promulgate

[178] *See, e.g.*, Eligible Obligations, Charitable Contributions, Nonmember Deposits, Fixed Assets, Investments, Fidelity Bonds, Incidental Powers, Member Business Loans, and Regulatory Flexibility Program, 77 Fed. Reg. 31981 (May 31, 2012) (to be codified at 12 C.F.R. pts. 701, 703, 713, 721, 723, 742) ("For the reasons discussed below the Board is adopting the amendments almost exactly as proposed. As such, the Board does not restate the legal analysis it presented in the NPRM's preamble and incorporates it by reference here in this rulemaking."); Crewmember Identification Documents, 74 Fed. Reg. 19135, 19139 (Apr. 28, 2000) (to be codified at 33 C.F.R. pt. 1360) ("We received no public comments that would alter our assessment of impacts in the NPRM. We have adopted the assessment in the NPRM as final.").

[179] *See, e.g.*, Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63692 (Nov. 7, 2003) (to be codified at 42 C.F.R. pts 400, 405, 426); *id.* at 63693 ("For further discussion of the claims appeal process please consult the proposed rule."); *id.* ("For the full discussion of NCDs please consult our proposed rule at 67 FR 54535 published on August 22, 2002."); *id.* ("The provisions described in bullets two through four above constitute coverage provisions. For further information on LMRPs please consult our proposed rule at 67 FR 54535.); Practices and Procedures, 77 Fed. Reg. 62,350, 62,350 (Oct. 12, 2012) (to be codified at 5 C.F.R. pts. 1200, 1201, 1203, 1208, 1209) ("[r]eaders desiring a more detailed summary of the amendments proposed by the MSPB should consult the proposed rule.").

[180] Exemption of Work Activity as a Basis for a Continuing Disability Review, 71 Fed. Reg. 66,840, 66,840 (Nov. 17, 2006) (to be codified at 20 C.F.R. pts. 404, 416).

the rule.[181] In the preamble, the Department of Labor stated "[w]e undertook this Rulemaking in accordance with 38 U.S.C. 4102A(c)(3)(B) (as enacted by the Jobs for Veterans Act) which requires the Department to establish that threshold rate by regulation."[182] Then the agency wrote "Section 4(a)(1) of the JVA amended 38 U.S.C. 4102A to require that the Secretary of Labor 'establish, and update as appropriate, a comprehensive performance accountability system . . . and carry out annual performance reviews of veterans employment, training, and placement services provided through employment service delivery systems, including through Disabled Veterans' Outreach Program specialists and through Local Veterans' Employment Representatives in States receiving grants, contracts, or awards under this chapter."[183]

After the agency recited what it was required to do by statute, the agency turned to discussing details of the rule, such as its definition of critical terms, but did not provide an independent statement reflecting the agency's choices about how best to implement the statutory requirement.[184]

2. Response to Comments

a. General Responses. Agencies frequently provide guidance about the meaning and application of their regulations in a dialogue with commenters in the preamble. They do this in different formats. Sometimes they do this in the course of a general response to comments. For instance, in a Department of Veterans Affairs (DVA) rule implementing the DVA's medical foster home program, a commenter asked whether the spouse of a married veteran could move into the medical foster home with the veteran or if the rule forced couples to live apart.[185] The DVA answered that "[n]othing in the regulation would preclude a spouse of a veteran from living in the same medical foster home as the veteran. Such an arrangement would be a matter of agreement between the spouse of the veteran and the medical foster home caregiver."[186] In this preamble, the DVA provided general guidance in response to comments without topical headings.

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[181] Uniform National Threshold Entered Employment Rate for Veterans, 78 Fed. Reg. 15,283, 15,283 (Mar. 11, 2013) (to be codified at 20 C.F.R. pt. 1001).
[182] *Id.* at 15,284.
[183] *Id.*
[184] *Id.*
[185] Medical Foster Homes, 77 Fed. Reg. 5,186, 5,187 (Feb. 2, 2012) (to be codified at 38 C.F.R. pt. 17); *see also* State Official Notification Rule, 77 Fed. Reg. 39112 (June 29, 2012) (to be codified at 12 C.F.R. 1082) (the following statement was the closest to a statement of purpose in the summary of the final rule: "In drafting the Final Rule, the Bureau endeavored to create a process that would provide both the Bureau and, where applicable, the prudential regulators with timely notice of pending actions and account for the investigation and litigation needs of state regulators and law enforcement agencies.").
[186] *Id.*

Agencies, however, often organize their general responses to comments by topic. For example, in a Department of Treasury and U.S. Customs and Border Protection (CBP) rule defining "members of a family" for purposes of filing a customs family declaration, the agencies responded to commenters in topical sections.[187] In the "Definition of Resident" section, a commenter posed a question about whether the definition of "resident" as used by CBP in this context was the same as "permanent resident" as used in the immigration law context.[188] The agencies responded that "[t]he term 'resident' for purposes of this regulation is not the same as 'lawful permanent resident' in immigration law. For customs purposes, pursuant to 19 CFR 148.2, persons arriving from foreign countries are divided into two categories: (1) Residents of the United States returning from abroad and (2) all other persons (i.e., visitors)."[189]

b. Section-by-Section Analysis. Agencies also provide guidance in the course of responding to comments through a section-by-section analysis. The Equal Employment Opportunity Commission (EEOC) used this format in a rule implementing Title II of the Genetic Information Nondiscrimination Act.[190] The EEOC offered guidance pertaining to numerical sections of the regulation, including "Section 1635.1 Purpose" followed by "Section 1635.2 Definitions—General."[191] In "Section 1635.3(a) Family Member," the EEOC confronted a commenter's suggestion that medical information obtained from one employee should not be considered family medical history of a family member who also works for the same employer.[192] The EEOC rejected this suggestion, writing, "[w]e do not think Congress could have intended that an employee not be protected from the discriminatory use or the disclosure of his or her genetic information just because the employer obtained it from a family member who was also an employee."[193]

The Small Business Administration (SBA) also utilized the section-by-section analysis format in a rule defining a new category of small business investment companies (SBICs).[194] Under the heading of "Section 107.50—Definitions," the SBA responded to a number of commenters that suggested changing the proposed definition of "Early Stage SBIC," by writing "SBA . . . believes the commenters' contrasting points of view

[187] Members of a Family for Purpose of Filing CBP Family Declaration, 78 Fed. Reg. 76,529, 76,529 (Dec. 18, 2013) (to be codified at 19 C.F.R. pt. 148).
[188] *Id.* at 76,530.
[189] *Id.*
[190] Regulations Under the Genetic Information Nondiscrimination Act of 2008, 75 Fed. Reg. 68,912, 68,912 (Nov. 9, 2010) (to be codified at 29 C.F.R. pt. 1635).
[191] *Id.* at 68,913.
[192] *Id.* at 68,915.
[193] *Id.* at 68,916.
[194] Small Business Investment Companies—Early Stage SBICs, 77 Fed. Reg. 25,042, 25,042 (April 27, 2012) (to be codified at 13 C.F.R. pt. 107).

illustrate the benefits of maintaining the flexibility that the proposed definition provided. SBA expects that some management teams will focus exclusively on early stage companies, while others will opt for a mixed portfolio."[195] This rule also includes a "General Comments" section where the SBA responds to comments that impact broad issues in the rule.[196] Agencies frequently combine two formats in their rules as the SBA did here.

c. Question-And-Format. Another method agencies use to respond to comments is the question and answer format. The Railroad Retirement Board (RRB) used this approach in a rule that removes a listing of impairments from its regulations and explains how the RRB will determine disability.[197] The preamble is divided into sections including, "What Programs Will the Final Rule Affect?" and "How Is Disability Defined?"[198] In the section, "How Does This Final Rule Address That Problem?", the RRB responds to commenters by stating "[t]he Board has reviewed the comments and the amendments to section 220.178(c)(1) and agrees that the second sentence could be confusing. We have modified that sentence to make it clear that in a continuing disability review, the claimant's current severity will be compared to the standard that was used to make the original, or 'comparison point decision.'"[199] Unlike the SBA rule, question and answer format is the only format used in this preamble.

A Social Security Administration (SSA) rule revising medical criteria used for evaluating digestive disorders utilized a combination of the question and answer format, section-by-section analysis, and general response to comments format.[200] The preamble begins with sections entitled, "Why are we revising the listings for digestive disorders?" and "What general changes are we making that affect both the adult and childhood listings for digestive disorders?"[201] Then, within these larger sections, SSA includes subsections with questions associated with particular regulatory text sections, such as "5.00D—How do we evaluate chronic liver disease?"[202] Next, SSA includes a "Public Comments" section that is a general response to comments.[203] Guidance appears throughout these different formats. For instance, in the "Public Comments" section, one commenter suggested that all individuals who require feeding through intravenous or gastrostomy tubes should be

[195] *Id.* at 25050.
[196] *Id.* at 25043.
[197] Removal of Listing of Impairments and Related Amendments, 74 Fed. Reg. 63,598, 63,598 (Dec. 4, 2009) (to be codified at 20 C.F.R. pt. 220).
[198] *Id.*
[199] *Id.* at 63,599–63,600.
[200] Revised Medical Criteria for Evaluating Digestive Disorders, 72 Fed. Reg. 59,398, 59,398 (Oct. 19, 2007) (to be codified at 20 C.F.R. pts. 404, 416).
[201] *Id.*
[202] *Id* at 59,399.
[203] *Id.* at 59,407.

considered not able to work under the rule, but the SSA responded that "we do not think it appropriate to presume disability in all individuals who need such treatment; we must evaluate most situations on a case-by-case basis."[204] Agencies rarely combine three or more formats to respond to comments as SSA did in this rule.

d. Detailed Examples. A fourth method that agencies use to provide guidance in preambles while responding to comments is through the use of detailed examples. These can be incorporated within any of the other three formats discussed above. The Department of Education included detailed examples in a rule amending the Direct Loan Program.[205] The agency wrote "[t]he following two examples illustrate the operation of the final regulations" and then "Example 1: Borrower A and Borrower B are both enrolled half-time and both enrolled in the fall term only. Borrower A receives a Direct Subsidized Loan in the amount of the annual loan limit and Borrower B receives a loan for less than the annual loan limit."[206] Following this introduction to the example, the Department of Education included a chart and a few paragraphs explaining how the hypothetical borrowers would be impacted by the regulation.[207]

The Centers for Medicare & Medicaid Services (CMS) also used detailed examples in the preamble to a rule establishing guidelines for Accountable Care Organizations (ACOs).[208] For instance, commenters expressed confusion over a proposed requirement that the governing bodies of ACOs at least 75% controlled by Medicare-enrolled entities. CMS responded with an example: "For example, if a hospital, two physician groups, and a health plan formed an ACO, the hospital and two physician groups must control at least 75 percent of the ACO governing body."[209] This example is embedded in a general response to comments section, but agencies frequently use examples and incorporate them in various formats.

3. Preambles the Appear to Bind

Rather than articulating the basis and purpose of the regulatory text or providing guidance on how to comply with it, some preambles make statements that appear or purport to have legal effect.

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[204] *Id.* at 59,409.
[205] William H. Ford Federal Direct Loan Program, 79 Fed. Reg. 3,108, 3,108 (Jan. 17, 2014) (to be codified at 34 C.F.R. pt. 685).
[206] *Id.* at 3,114 – 3,115.
[207] *Id.* at 3,115.
[208] Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,802 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).
[209] *Id.* at 67,819–67,820.

A complex rulemaking by the Centers for Medicare and Medicaid Services (CMS) provides an example of the slippage that can occur between the preamble and the text of the rule.[210] In the rule, CMS revised requirements for the way in which long-term care hospitals transfer patients to hospitals within them ("hospitals within hospitals") or affiliated satellite hospitals. In the preamble to its final rule, CMS noted in response to comments that it provided a 4-year transition prior for the implementation of the new requirements and also provide for certain hospitals to be "grandfathered," treating the first year as "hold harmless."[211] The preamble went on to state, "we are requiring that even for grandfathered facilities, in the first cost reporting period, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period."[212]

The final rule, however, "omitted the limitation that grandfathered facilities in the first year of the transition period would not be allowed to exceed the percentage of patients admitted from the host during fiscal year 2004 cost reporting period."[213] The preamble thus stated a requirement about the percentage of permissible admissions to hospitals within hospitals and satellite facilities that did not appear in the rule.

On its own initiative, CMS issued a correcting amendment to the rule to conform the rule to its preamble's statement of the requirements applicable to grandfathered institutions,[214] which correcting amendment was upheld from procedural and substantive challenges.[215]

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[210] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, 69 Fed. Reg. 48916 (Aug. 11, 2004) (to be codified at 42 CFR pts. 403, 412, 413, 418, 460, 480, 482, 483, 485, 489).
[211] *Id*. at 49196.
[212] *Id*.
[213] Select Specialty Hosp.-Akron v. Sebelius, 820 F.Supp.2d 13, 23-24 (D.D.C 2011).
[214] *Id.*
[215] Id. at 27 (concluding that the agency was not required to go through another round of notice-and-comment to issue its correcting amendment and that the amendment was not arbitrary nor capricious). See also Natural Res. Def. Council v. EPA, 559 F.3d 561, 565 (D.C. Cir. 2009) (invalidating requirements stated in preamble that did not correspond to or interpret a section of the rule). In some cases, agencies make statements in their preambles that appear to be binding in part because they use mandatory language and do not make a reference the regulatory text, even when the regulatory text provides a basis for the obligations discussed. *See, e.g.*, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,898-99 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425) (in a section headed "Final Decision" the preamble stated "if an ACO [Accountable Care Organization] fails to achieve the minimum attainment level on at least 70 percent of the measures in each domain, we will give the ACO a warning, an opportunity to resubmit and re-evaluate the following year. If the ACO continues to underperform in the following year, the agreement would be terminated," without referring to 42 CFR § 425.502(d)(2)(ii)). It is preferable to for mandatory statements of this kind in preambles to cite the regulatory provisions that give rise to those obligations.
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C. Guidance in Regulatory Text and Appendices

Agencies provide guidance about the meaning and application of their regulations in the regulatory text itself and in appendices attached to final rules. While guidance in the regulatory text appears, by definition, in the Code of Federal Regulations, guidance in appendices is sometimes only published in the Federal Register and other times published in the Code of Federal Regulations. Agencies choose a number of different formats to provide guidance in the regulatory text and appendix, including through official commentary, examples, question and answer format, and technical guidance. The following sections illustrate the various ways agencies offer guidance in the regulatory text and appendix.

1. Guidance Published in the CFR

a. Examples in Regulatory Text. Agencies provide guidance in material published in the CFR, most often in the form of notes and examples. For instance, the Department of the Treasury provided illustrative examples in a rule on mergers, acquisitions, and takeovers by foreign persons.[216] In § 800.215 (a)–(b), the regulatory text defines a "foreign person" as "(a) Any foreign national, foreign government, or foreign entity; or (b) Any entity over which control is exercised or exercisable by a foreign national, foreign government, or foreign entity."[217] After this text, there are five examples illuminating the "foreign person" definition.[218] Example 4 states that "[c]orporation A is organized under the laws of a foreign state and is owned and controlled by a foreign national. A branch of Corporation A engages in interstate commerce in the United States. Corporation A (including its branch) is a foreign person. The branch is also a U.S. business."[219] After the examples, the rule proceeds to the next regulatory provision.[220]

The Merit Systems Protection Board (MSPB) provided guidance through examples in the regulatory text of a rule updating MSPB's adjudicatory practices and processes.[221] In its rule addressing the filing of appeals, the Board notes that "[a]n appellant is responsible for keeping the agency informed of his or her current home address[.]"[222] Following the

[216] Regulations Pertaining to Mergers, Acquisitions, and Takeovers by Foreign Persons, 73 Fed. Reg. 70,702, 70,702 (Nov. 21, 2008) (to be codified at 31 C.F.R. pt. 800).
[217] *Id.* at 70,720.
[218] *Id.*
[219] *Id.*
[220] *Id.*
[221] Practices and Procedures, 77 Fed. Reg. 62,350, 62,350 (Oct. 12, 2012) (to be codified at 5 C.F.R. pts. 1200, 1201, 1203, 1208, and 1209).
[222] *Id.* at 62,364.

rule's text, the Board provided examples "to illustrate the application of this rule."[223] The three enumerated examples include: "Example A: An appellant who fails to pick up mail delivered to his or her post office box may be deemed to have received the agency decision. Example B: An appellant who did not receive his or her mail while in the hospital may overcome the presumption of actual receipt. Example C: An appellant may be deemed to have received an agency decision received by his or her roommate."[224] Since these examples are part of the regulatory text, they are published in the Code of Federal Regulations.[225]

2. Guidance in Appendix

a. Official Commentary in Appendix. Some agencies incorporate official commentary, official interpretations, or designated interpretive guidance into appendices. The Equal Employment Opportunity Commission (EEOC) included official interpretations in a rule implementing the equal employment provisions of the ADA Amendments Act of 2008.[226] In the preamble to the final rule, the EEOC explained the function of the official interpretations:

> The appendix addresses the major provisions of the regulations and explains the major concepts. The appendix as revised will be issued and published in the Code of Federal Regulations with the final regulations. It will continue to represent the Commission's interpretation of the issues discussed in the regulations, and the Commission will be guided by it when resolving charges of employment discrimination under the ADA.[227]

The appendix entitled "Appendix to Part 1630—Interpretive Guidance on Title I of the Americans with Disabilities Act" includes a lengthy introduction on the development of the ADA followed by a section-by-section analysis of the provisions promulgated in the regulation.[228] For instance, in the appendix under "Section 1630.2(l) – Regarded as Substantially Limited in a Major Life Activity", the EEOC wrote "[c]overage under the 'regarded as' prong of the definition of disability should not be difficult to establish."[229]

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[223] *Id.*
[224] *Id.*
[225] *Id.*
[226] Regulations To Implement the Equal Employment Provisions of the Americans With Disabilities Act, as Amended, 76 Fed. Reg. 16,978, 16,978 (March 25, 2011) (to be codified at 29 C.F.R. pt. 1630).
[227] *Id.* at 16979.
[228] *Id.* at 17003.
[229] *Id.* at 17014.

The EEOC states that these interpretations will guide it when resolving employment discrimination charges under the ADA.[230]

The Consumer Financial Protection Bureau (CFPB) also included official interpretations at the end of Regulation X, a rule implementing the Real Estate Settlement Procedures Act (RESPA).[231] After appendices with technical guidance, there is a section entitled "Supplement I to Part 1024—Official Bureau Interpretations."[232] In this supplement, the CFPB explains that "[t]his commentary is the primary vehicle by which the [Bureau] issues official interpretations of Regulation X. Good faith compliance with this commentary affords protection from liability under section 19(b) of [RESPA]."[233] Like the EEOC rule above, this supplement included section-by-section interpretations of the regulation.[234] For instance, in the supplement the CFPB interpreted the regulatory provision § 1024.36 on investigation and response requirements.[235] Specifically, the agency interpreted "information not available" as occurring when: "(i.) [t]he information is not in the servicer's control or possession, or (ii) [t]he information cannot be retrieved in the ordinary course of business through reasonable efforts."[236]

b. Examples in Appendix. The EEOC appendix that provided interpretive guidance on the ADA Amendments Act of 2008 also incorporated examples.[237] In the appendix, the EEOC wrote: "[f]or example, an individual who is denied a promotion because he has a minor back injury would be 'regarded as' an individual with a disability if the back impairment lasted or was expected to last more than six months."[238] The EEOC offered numerous examples in this appendix.

A joint rule by a group of agencies (Treasury, SSA, DVA, RRB, and OPM) on garnishment of accounts containing federal benefit payments utilized examples in an appendix to the final rule.[239] For instance, one of the appendices entitled "Appendix C to Part 212—Examples of the Lookback Period and Protected Amount" stated "the following

[230] *Id.* at 16978.
[231] Mortgage Servicing Rules Under the Real Estate Settlement Procedures Act (Regulation X), 78 Fed. Reg. 10,696, 10,696 (Feb. 14, 2013) (to be codified at 12 C.F.R. pt. 1024).
[232] *Id.* at 10,887.
[233] *Id.*
[234] *Id.*
[235] *Id.* at 10,891.
[236] *Id.*
[237] Regulations To Implement the Equal Employment Provisions of the Americans With Disabilities Act, as Amended, 76 Fed. Reg. 16,978, 17,016 (March 25, 2011) (to be codified at 29 C.F.R. pt. 1630).
[238] *Id.*
[239] Garnishment of Accounts Containing Federal Benefit Payments, 78 Fed. Reg. 32,099, 32,110 (May 29, 2013) (to be codified at 31 C.F.R. pt. 212).

examples illustrate the definition of *protected amount*."[240] There are then five examples that explain how hypothetical scenarios fit within the definition of protected amount.[241] Here is an excerpt of example 4: "Since the $2,000 sum of the two benefit payments posted to the account during the lookback period is less than the $3,000 balance in the account when the account review is performed, the financial institution establishes the protected amount at $2,000 and places a hold on the remaining $1,000 in the account in accordance with State law."[242] The appendices were published in the CFR.

c. Question and Answer Format in Appendix. Agencies provide guidance in appendices through the question and answer format. The Social Security Administration promulgated a rule revising medical criteria for evaluating visual disorders in which revisions adopted consisted almost exclusively amendments to the appendix appearing in the CFR.[243] After the preamble, the agency posed and answered a series of questions in the appendix.[244] Questions included, for instance, "How do we evaluate visual disorders?" and "How do we define statutory blindness?"[245] In response to the question "What are visual disorders?", the agency wrote "Visual disorders are abnormalities of the eye, the optic nerve, the optic tracts, or the brain that may cause a loss of visual acuity or visual fields."[246] These questions and answers in the appendix were published in the Code of Federal Regulations.

The Department of Education also provided guidance in an appendix through the question and answer format in a rule implementing the Family Educational Rights and Privacy Act (FERPA).[247] After the regulatory text, the Department of Education included a document on "Guidance for Reasonable Methods and Written Agreements" in Appendix A.[248] The Department of Education structured this guidance document as a series of questions and answers.[249] Questions included: "What is the Family Educational Rights and Privacy Act?" and "What do I do if the terms of the written agreement are violated?"[250] In response to the latter question, the agency answered "[i]f the entity to which you have disclosed PII from education records without consent . . . violates the terms of the written

[240] *Id.* at 32,109.
[241] *Id.* at 32,109–32,110.
[242] *Id.* at 32,110.
[243] Revised Medical Criteria for Evaluating Visual Disorders, 78 Fed. Reg. 18,837, 18,837 (March 28, 2013) (to be codified at 20 C.F.R. pt. 404).
[244] *Id.* at 18839.
[245] *Id.*
[246] *Id.* at 18,834
[247] Family Educational Rights and Privacy, 76 Fed. Reg. 75,604, 75,645 (Dec. 2, 2011) (to be codified at 34 C.F.R. pt. 99).
[248] *Id.*
[249] *Id.*
[250] *Id.* at 75,645, 75,653.

agreement, you should evaluate your options under the penalty and termination provisions of the agreement . . . ."[251] Interestingly, before the appendices to the FERPA rule, the Department of Education wrote "Note: The following appendices will not appear in the Code of Federal Regulations."[252] (The agency did not further explain its choice to exclude the appendices from the CFR.)

d. Technical Guidance in Appendix. Agencies sometimes include technical guidance in appendices to final rules. For instance, the CFPB utilized this approach in Regulation X discussed above.[253] After the regulatory text, the CFPB attached appendices with model forms and sample language for use by regulated entities.[254] Appendix MS-2 contained a model form of a notice of transfer of loan servicing for a servicer to provide to a borrower.[255] An excerpt of this model form read: "[Name of present servicer] is now collecting your payments. [Name of present servicer] will stop accepting payments received from you after [Date]."[256] These model forms were published in the CFR.

The Department of Education's rule implementing FERPA also includes technical guidance in appendices.[257] FERPA requires educational institutions to annually notify parents and eligible students of their rights under FERPA.[258] To facilitate this requirement, Appendix B attached to the final rule includes a "Model Notification of Rights under FERPA for Elementary and Secondary Schools."[259] The model form begins with "[FERPA] affords parents and students who are 18 years of age or older ('eligible students') certain rights with respect to the student's education records" and then the model form enumerates those rights.[260] As mentioned previously, the appendices to the FERPA rule were not published in the CFR.

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[251] *Id.* at 75,653.
[252] *Id.* at 75644. So long as the material is reasonable available, as it was in this case, this practice complies with recommended practices on incorporation by reference. See Admin. Conf. of the United States, Agency Policy Statements, Recommendation 2011-5, ¶ 1, 77 Fed. Reg. 2257, 2258 (Jan. 17, 2012) (recommending that material incorporated by reference be reasonably available).
[253] Mortgage Servicing Rules Under the Real Estate Settlement Procedures Act (Regulation X), 78 Fed. Reg. 10,696, 10,886 (Feb. 14, 2013) (to be codified at 12 C.F.R. pt. 1024).
[254] *Id.*
[255] *Id.* at 10,877.
[256] *Id.* at 10,886.
[257] Family Educational Rights and Privacy, 76 Fed. Reg. 75,604, 75,654 (Dec. 2, 2011) (to be codified at 34 C.F.R. pt. 99).
[258] *Id.* at 75608.
[259] *Id.* at 75654.
[260] *Id.*

D. Separately Issued Contemporaneous Guidance

Agencies frequently issue guidance or draft guidance in the form of separately issued documents at the time that they issue their rules. Issuing guidance at the same time as a rule is issued has a nice benefit of giving regulated parties as much notice as possible at the time the rule promulgated about its effect, though it can cause some delays because the same agency staff members that draft rules and preambles also often involved in drafting guidance documents.

The Nuclear Regulatory Commission (NRC) provides a recent example an agency issuing guidance alongside a new rule. At the time the NRC issued a rule amending its regulations regarding the security requirements for the transportation of radioactive material,[261] it also issued an extensive guidance document to assist in the implementation of these requirements.[262] The implementation guidance provided comprehensive treatment of the approaches and methods that the agency deemed acceptable in complying with the regulations,[263] framing this guidance in an accessible question-and-answer format. The practice of issuing a freestanding guidance at the same time a rule is promulgated is particular helpful where, as in the case of the NRC rule, [264] the preamble makes reference to (and providing links to) the accompanying guidance.

Even when agencies choose not to issue a separately designated guidance document, as noted above, for rules with significant impacts on small entities, SBREFA requires agencies to issue a form of contemporaneous guidance, "small entity compliance guidance," before the regulation becomes effective to explain what actions are necessary for a small entity to comply with the regulation.[265]

In 2001, GAO issued a report concluding that many agencies were failing to fully comply with these requirements of SBREFA.[266] Based on an examination of rulemaking in 1999 and 2000 for seven agencies (the Department Commerce, CMS, FDA, HHS, EPA, FCC, and SEC), the GAO study concluded that agencies were applying different standards for when a rule affected small entities triggering the obligation to prepare a guide,[267] were

[261] Nuclear Regulatory Commission, Physical Protection of Byproduct Material, Final Rule, 78 Fed. Reg. 16922 (Mar. 19, 2013).
[262] U.S.N.R.C., Office of Federal and State Materials and Environmental Management Programs, Implementation of Guidance for 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," NUREG-2155 (Feb. 2013).
[263] Id. at 1.
[264] *See* Physical Protection of Byproduct Material, 78 Fed. Reg. at 16922.
[265] Small Business Regulatory Enforcement Fairness Act, § 212(a)(4)(B)(i), 5 U.S.C. § 610 (2006)
[266] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO 02-172, Compliance Guide Requirement Law Little Effect on Agency Practices (2001).
[267] *Id.* at 14.

not designating their products as "compliance guides,"[268] were failing to explain the compliance actions required,[269] and did not meet the contemporaneous deadlines set by the Act,[270] among other difficulties. Interestingly, there is no central clearing house for these compliance guides; they are posted on agency websites, but not gathered for ease of access, say, by the Small Business Administration or OMB.

V. Recommendations to Federal Agencies

This Part sets forth recommendations to federal agencies with regard to the use of contemporary guidance. Some recommendations apply generally and others pertain to specific agencies or practices. Some suggest relatively substantive reforms, such as in preamble drafting and internal review processes, whereas others pertain to how agencies structure their web content. They are grouped under topical headings.

1. Preamble Drafting

Rec. 1.1. The statement of "basis and purpose" produced in the preamble to final rules should state the purpose of the rule and how it advances statutory objectives in a way that goes beyond merely repeating the statutory title or language.

Discussion: Recommendation 1.1 is based on the principle that an agency's own statement of the purposes of the rule in light of statutory objectives is a necessary element of the "statement of basis and purpose" under APA § 553 and "a statement of the need for, and objectives of, the rule" under the Regulatory Flexibility Act (RFA).[271] While the vast majority of agencies and rulemakings admirably comply with this basic requirement, there is a role for ACUS in highlighting the importance of compliance with this fundamental duty. This principle follows from judicial interpretations of the APA and RFA discussed above. At a basic level, statement of a rule's purpose and how it advances statutory objections orients all interpretation of the rule, and demonstrates the agency's discharge of the statutory powers with which it is vested.

For those concerned about the burden this recommendation places on agencies, it is worth emphasizing three points. First, this is a fundamental requirement of the APA and RFA, but one for which there is not active judicial enforcement for many rules. Second, compliance with this recommendation should not be unduly burdensome. For small and

[268] *Id.* at 23.
[269] *Id.* at 24.
[270] *Id.* at 28.
[271] 5 U.S.C. § 604 (2012).

routine rulemakings, the agency could comply with this recommendation with a sentence or two of explanation. Third, this recommendation addresses only those rule that proceed through notice and comment. Regulations that merely restate the language of statutes they implement need not proceed through notice-and-comment,[272] and therefore fall outside this recommendation (along with other rules exempted from notice and comment).

Rec. 1.2. Agencies generally should organize their preambles to include a section-by-section analysis in which the organization of the preambular discussion corresponds to the organization of the final rules themselves to facilitate identification of the guidance the agency has provided as to each provision of the rule.

Discussion: The increased justificatory demands on preambles, as discussed above, have contributed to the length and complexity of these documents. Recommendation 1.2 is the organizational equivalent of a requirement for plain language. It reflects the common sense idea that when the preamble is organized according to the sections of the rule, it is easier for those reading them to locate the most highly pertinent discussion. Of course, reading a section-by-section analysis is no excuse for not reading the entire preamble in order to understand its context and cross-cutting implications. But such an organizational structure reduces the search costs for those seeking to understand the operation and justification for particular aspects of an agency rule. In other words, a well-organized preamble reduces the cost of using it for guidance. Recommendation 1.2 is one modest way of addressing how the justificatory role of preambles has obscured their utility as guidance documents.

Rec. 1.3. Agencies should strive for preambles to their final rules to be comprehensive statements of each rule's basis and purpose and should generally avoid relying in on discussions of these matters in the Notice of Proposed Rulemaking (or other prior notices) in ways that require the reader to integrate two or more prior discussions of the rule's basis and purpose.

Discussion: Recommendation 1.3 addresses the practice of incorporating the background discussion of the policy, basis, and objections provided in the Notice of Proposed Rulemaking (and other prior notices) in the final preamble. The Office of the Federal Register charges agencies per page they print in the Federal Register,[273] so

[272] Gray Panthers Advocacy Cmm.., 936 F.2d 1284, 1291 (1991) ("when regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary").

[273] The fees for Federal Register publication in FY 2014 are as follows: MS Word submission: $477/per page, $159/per column; Manuscript Copy: $522/per page, $174/per column; Camera Copy: $522/per page, $174/per column. *See* Government Printing Office, Circular Letter No. 885 to Printing and Publishing

agencies have some incentive to incorporate prior analysis in a final preamble as opposed to restating them. Moreover, sometimes rules and their supporting analysis change very little in the comment process. Relying on prior discussions can also save agency drafters time. Notwithstanding these considerations, the practice of relying on analysis and discussion in previously published notices or other documents in the same rulemaking impedes the guidance function of the final rule's preamble. With extensive reliance on prior statements of the rule's basis and purpose, the final preamble becomes merely a placeholder and signpost to other analyses that need to be integrated with the text of the final preamble. Requiring the public and regulated parties to integrate two or more separate and partial agency discussions of the basis and scope of the rule complicates the utility of these statements for guidance purposes. This suggests that agencies should, at a minimum, consider whether incorporating or relying upon prior analysis will impede the guidance function of their preamble, and generally avoid such incorporation when it requires a reader to integrate two or more discussions.[274] At a more general level, the guidance function of the final preamble is best served when the preamble provides a comprehensive statement of the rule's basis and purpose and the agency's views about is application.

Rec. 1.4. Agencies should not make statements of general applicability that are intended to have legal effect, such statements imposing binding substantive standards or obligations, in preambles to final rules.

Discussion: While preambles may be authoritative sources of guidance, as discussed above, under the APA, preambles should not include legislative rules; if a preamble were to include a legislative rule, that rule would be procedurally invalid under APA § 553. ACUS Recommendation 92-2 states that agencies should "not issue statements of general applicability that are intended to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures (normally notice-and-comment)."[275] Recommendation 1.4 makes clear that the general prohibition on including statements that are intended to have legal effect applies to preambles to final rules. This recommendation also finds support in *OMB's Good Guidance Bulletin*. The *Bulletin* prohibits agencies from using mandatory language in guidance documents unless "the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose

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Officials of the Federal Government (May 31, 2103) (available at http://www.gpo.gov/pdfs/customers/cir885.pdf) (last visited March 31, 2014).

[274] Relying entirely on a previous statement of the basis and purpose for the rule is less problematic in the sense that it requires less integration of two separate discussions.

[275] Admin. Conf. of the United States, Agency Policy Statements, Recommendation 92-2, 57 Fed. Reg. 30,103 (June 18, 1992).

consideration by the agency of positions advanced by affected private parties."[276] The *Bulletin* gives "shall," "must," and "requirement" as examples of prohibited mandatory language, but these words are only illustrative. Recommendation 1.4 highlights that the prohibition applies to all statements that purport to specify legal effects, not just those singled out by the mandatory language identified in *OMB's Good Guidance Bulletin*.

2. Integrating Preambles into Policies on Guidance and Collection of Guidance

Rec. 2.1. Agencies should mention preambles to their final rules as sources of guidance in their general compilations of guidance and on their webpages devoted to guidance. Agencies should also develop ways to integrate the guidance content of their preambles into their general compilations of guidance and their webpages devoted to guidance.

Discussion: The preambles to final rules are often the most important sources of guidance about the rule's meaning and effects. *OMB's Good Guidance Bulletin* requires, as noted above, "each agency to maintain on its Web site . . . a current list of its significant guidance documents in effect."[277] These pages typically define guidance and provide a topical and/or chronological listing of the agency's guidance documents, with links. Based on a review of those executive agencies which have issued an economically significant rule in the last 15 years,[278] only the Department of Transportation mentions preambles as sources of guidance. Recommendation 2.1 seeks to improve the visibility of preambles as sources of guidance by recommending that, at a minimum, agencies mention preambles to final rules on these guidance web pages and integrate them into their general compilations of guidance.

There is not likely to be a uniform way to integrate guidance content of preambles into agency's web-based summaries of guidance. By endeavoring to do integrate the guidance content of their preambles into their topical and other treatments of guidance, the agencies will not only assist the public in identifying this content but also will be spurned to consider how the guidance content of their preambles relates to the guidance they later provide. This process may encourage agencies to make self-conscious choices about the allocation of their guidance content between final preambles and later issued guidance documents, and overcome residual perceptions preambles concern only legal sufficiency

[276] *OMB's Good Guidance Bulletin*, *supra* note 1, at 3440.
[277] *See id*. at Section III.1
[278] This list of agencies is drawn from. LEWIS & SELIN, *supra* note 66, at 132 Table 20. The web pages for these agencies were visited in March 2014.

and thus need not be considered as part of the way in which the agency provides guidance about the meaning of its regulations.

The recommendation applies not only to those agencies covered by *OMB's Good Guidance Bulletin* but to all agencies. The reason is that integrating the guidance in preambles into presentations of agency guidance will promote the visibility of this guidance regardless of the type of agency.

Rec. 2.2. To the extent agencies have policies on issuing guidance, those policies should address the guidance content of preambles to their final rules. For agencies covered by *OMB's Good Guidance Bulletin*, their policies should address compliance with the *Bulletin's* procedural requirements applicable to any significant guidance documents and economically significant guidance included in preambles to final rules.

Discussion: The analysis of the *OMB's Good Guidance Bulletin* above suggests that guidance provided in preambles, if significant, is subject to the provisions of the *Bulletin*. As a result, conscientious compliance with that *Bulletin* (or careful monitoring of compliance with it by OMB) would require evaluating whether guidance provided in preambles triggers any of the process or other requirements of the Bulletin. Recommendation 2.2 advises agencies to incorporate the guidance content of their preambles into their procedures for approval and review of guidance, as well as, when applicable, the procedural requirements imposed by the *Bulletin*.

3. Electronic Presentation of Regulations with Hyperlinks

Rec. 3.1. Working in conjunction with the Office of the Federal Register and the Government Printing Office, agencies should develop ways to display their regulations in electronic form on their websites in ways that include hyperlinks to relevant guidance in the rules' final preambles as well as to other relevant guidance documents.

Discussion: It could be helpful to the public and regulated entities for agencies to utilize the possibilities of hypertext (text with hyperlinks) in electronic presentation of their regulations. The Consumer Financial Protection Bureau, for instance, has piloted a new online tool, "eRegulations,"[279] with the aim of improving access to final rules.[280] The tool provides navigable links to defined terms, official commentary, previous and future

[279] E-Regulations, http://www.consumerfinance.gov/eregulations/1005 (last visited Mar. 21, 2014).
[280] *See* Stephanie J. Tatham, *CFPB's eRegulations tool promises to help users navigate federal regulations*, ADMINISTRATIVE FIX BLOG, (Oct. 22, 2013, 6:11 PM), http://www.acus.gov/newsroom/administrative-fix-blog/cfpb%E2%80%99s-eregulations-tool-promises-help-users-navigate-federal

versions of the rule, as well as section-by-section analysis in regulatory preambles.[281] This tool is an important step in realizing the possibilities of the internet and hypertext formats to improve access regulations. In particular, tools, like CFPB's, that link the relevant sections of preambles to the rule provisions, clearly highlight the guidance function of preambles and also reduce the costs associated with accessing this preamble guidance. Interestingly, the adoption of such hyperlink tools may also influence the way in which preambles are drafted, in particular by giving agencies incentives to write preambles with organizational structures (as suggested by Recommendation 1.2) that track the rule's sections so that they can support intelligible hyperlinks. Agencies are likely to be in the best position to identify what documents and portions of preambles should be hyperlinked. In addition, the Office of the Federal Register and the Government Printing Office should be encouraged to work with agencies to make available electronic versions of agency regulations with these hyperlinks in the official versions of the Federal Register and Code of Federal Regulations the Office of the Federal Register maintains.

4. Tailoring Location of Guidance to the Practices of Those Regulated

Rec. 4.1. Where the regulated population is (1) primarily the public and (2) is understood to rely primarily on the codified regulation text to understand their compliance obligations, agencies should consider including the guidance (such as notes and example applications) in the text of the Code of Federal Regulations or in an appendix to the Code of Federal Regulations, as opposed to including it only in a separate guidance document or a preamble.

Discussion: Most members of the public and many regulated parties have little knowledge of administrative government, much less the distinction between a "regulation" and "guidance." Members of the public frequently and reasonably seek the simplest way to find out what the law requires. When the agency publishes guidance in the form of examples, technical advice, or official interpretations, it can improve the accessibility of this content if it is published in the Code of Federal Regulations, either as a note or example in the text or as an appendix. Recommendation 4.1 suggests that when the public is the primary regulated audience and the agency has reason to believe that the public relies primarily on the Code of Federal Regulations to ascertain its compliance obligations, the agency should consider including that guidance in the Code of Federal Regulations. One possible downside of publishing guidance in the CFR is that the public will take it too

[281] *See id.*

seriously, or treat it as binding (not just as authoritative guidance).[282] This is a real risk, and so agencies issuing guidance in the CFR should clearly designate that it is nonbinding.

Publishing guidance content in the CFR also imposes an additional process burden on the agency. But, as noted above, under *Alaska Professional Hunters*, the agency would have to proceed through notice-and-comment to revise any authoritative guidance, so issuing it in the CFR does not increase the agency's revision cost, only its cost for issuance. Agencies thus will have to make case specific determinations about whether the increased cost (or delay) of issuing the content in the CFR outweigh the benefit of making this content more accessible to its regulated public (and not create too great a risk that the public will treat it as binding).

5. Small Entity Compliance Guides

Rec. 5.1. Agencies should reassess how they are displaying the small entity compliance guides on their websites to ensure that these guides are in an "easily identified location"[283] as required by Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

Rec. 5.2. The Small Business Administration should work with agencies to develop guidelines for posting small entity compliance guides on agency websites in ways that make them easily identifiable.

Rec. 5.3. The Small Business Administration should maintain a webpage with links to agency webpages that host the agency's small entity compliance guides.

Discussion of 5.1-5.3: While many agencies make the small entity compliance guides required by SBREFA to be an "easily identified location" on their websites, for many agencies these guides are difficult to find. Indeed, searching the websites of the 21 agencies that have issued an economically significant rule in the past 15 years,[284] only four agencies (Labor, State, Transportation, and EPA) has a web page devoted to displaying

[282] For instance, the Department of Energy decided to delete guidance that had appeared as an appendix in the C.F.R. and publish the same in an updated form on its web site. *See Energy Conservation Program: Test Procedures for Electronic Motors and Small Electric Motors*, 77 Fed. Reg. 26608, 26623-24 (May 4, 2012) (to be codified at 10 C.F.R. pt. 431). The Department noted that his change "does not change the legal effect or authority of appendix A as appendix A was a 'Policy Statement' that merely provided users with guidance as to DOE's interpretation of existing statutes and regulations." *Id.* Placing this content in freestanding guidance, the Department explained will allow the Department "to respond more efficiently to questions" and also "eliminate any potential confusion as to the legal effect of appendix A." *Id.*

[283] 5 U.S.C. § 601 nt. § 212(a)(2(A) (2012).

[284] See Lewis & Selin, *supra* note 17, at 132. Web searches of these agency websites conducted in March, April, and May 2014.

these guides. It does not make sense to require agencies to produce these guides, as SBREFA does, and not follow through on making them readily accessible. In this regard, agencies should be encouraged to evaluate where they are posting these guidance on their web sites, as provided in Rec. 5.1

Rec. 5.2 encourages the Small Business Administration (SBA) to take a leadership role in coordinating among agencies and developing policies on uniform and best practices for agencies presenting small entity compliance guides on their websites. Because these guides are directed to small entities, the Small Business Administration is a logical leader for this endeavor.

Rec. 5.3 goes a step further and recommends that SBA host clearinghouse with links to agency webpages that contain their small entity compliance guides. Such a clearinghouse would provide a backstop for small entities searching for these guides; it would allow them to easily find where these guides are located for each agency, and may also alert them to other useful guides. Because these guides are directed to small entities, and the SBA already maintains a webpage with information about SBREFA, the SBA is a logical home for this clearinghouse.

Maintaining this clearinghouse would also create a welcome additional incentive for agencies to comply with the requirements of SBREFA. As noted above, GAO's 2001 report, *Compliance Guide Requirement Law Little Effect on Agency Practices*,[285] found that many agency compliance guides were not complying with all the requirements of this provision of SBREFA. A collection of links to agency webpages with these guides will make it easy for agencies to compare their guides to those produced by other agencies, and may create some pressure toward greater consistency in meeting the requirements SBREFA establishes. It will also provide enforcement for Rec. 5.2's recommendation for SBA to work with agencies to enhance the visibility of these guides.

[285] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO 02-172, COMPLIANCE GUIDE REQUIREMENT HAS HAD LAW LITTLE EFFECT ON AGENCY PRACTICES (2001).

Conclusion

Given that notice-and-comment regulations account for many more binding legal norms than statutes, the interpretation of regulations is a critical question for administrative governance. One critical source for understanding the meaning and application of regulations is agency's own guidance.

Agencies routinely provide guidance in the context of rulemaking. There is some minimum guidance function inherent in an agency's statement of basis and purpose in a regulation's preamble. But in many cases, agencies provide considerably more preamble guidance about the meaning of the regulation in the preamble. Agencies also do so in the regulatory text (including appendices that may be published in the CFR) and separate documents. But despite the ubiquity of contemporaneous guidance, it has been largely neglected in the long-running debate best guidance practices for agencies.

This Report seeks to take some initial steps in overcoming this neglect. It does so by pursuing three goals. First, by documenting the scope of contemporaneous guidance and its varieties, the Report aims to provide agencies with resources for making deliberate choices about the use of guidance in rulemaking. Second, by describing the legal regime applicable to contemporaneous guidance the Report aims to inform and prompt evaluation of current practices. Third, by tracing the implications of the neglect of the guidance function of preambles and use of regulatory text for guidance, the Report teases out several recommendations to improve the utility and accessibility of these guidance documents.

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